Exhibit B

Christopher S. Morris, MD

Bard IVC Filter Multi-District Litigation
Expert Report

Personal Background and Experience

I am an Interventional Radiologist with over 25 years of clinical experience at a busy tertiary care referral center. This includes the placement and retrieval of inferior vena cava filters (IVCFs), as well as the care and management of patients with IVCFs. I graduated from Case Western Reserve University School of Medicine in 1985 and completed an Internship in Internal Medicine at Cleveland Metropolitan General Hospital. My residency in Diagnostic Radiology was obtained at the Ohio State University Hospitals from 1986 to 1990 and my fellowship in Vascular and Interventional Radiology was obtained at the Massachusetts General Hospital from 1990 to 1991. My residency and fellowship were heavily weighted towards IVCFs. I trained with leaders in the field, including some of the first Interventional Radiologists, Drs. Van Aman and Stockum, to place Greenfield IVCFs percutaneously, which revolutionized the practice of IVCF insertion more than 30 years ago. Ohio State University Hospitals has a long tradition of innovation in Interventional Radiology, which stimulated my interest in this specialty. Drs. Van Aman and Stockum were trained by Dr. William Molnar, a Grandfather of Interventional Radiology who was instrumental in developing the technique of coronary and cardiac angiography, as well as long term percutaneous biliary drainage. A Founding Fellow of the Society of Cardiovascular and Interventional Radiology, Dr. Molnar was an emeritus Professor of Radiology who taught me during the early part of my residency. At Massachusetts General Hospital, I trained with Drs. Waltman and Athanasoulis, who are also distinguished Interventional Radiologists and experts in the field of IVCFs.

I serve as a Professor of Radiology and Surgery at the Robert Larner, MD College of Medicine at the University of Vermont, and teach residents, fellows, and medical students about IVCFs, including indications, contraindications, risks, and complications of IVCFs, as well as alternative therapies for venous thromboembolic disease. During this timeframe, I have taught and mentored more than 100 residents in Diagnostic Radiology as they rotated on the Interventional Radiology service, in addition to 28 fellows in Interventional Radiology, who worked closely with me on a daily basis. I co-founded the Fellowship in Interventional Radiology at the University of Vermont in 1994. I have served as the Program Director for the Diagnostic Radiology Residency, Program Director of the Fellowship in Interventional Radiology, and the Division Director of Interventional Radiology at the University of Vermont Medical Center (formerly Fletcher Allen Health Care, formerly Medical Center Hospital of Vermont).

I also taught Interventional Radiology colleagues about IVCFs as a member of the IVCF Workshop series during the annual national meeting of the Society of Interventional Radiology

for five years, during the introduction of optional IVCFs in the United States. I was the chair of this Workshop series for three years.

Over my career at the University of Vermont, I have been part of a small team of full time Interventional Radiologists, and have performed a large variety of vascular and non-vascular procedures that embodies the gamut of Interventional Radiology. Our practice has always been a blend of clinical Interventional Radiology and academics. I have focused on building a busy and well respected Interventional Radiology service and have strived to become the best versatile and well rounded, full time clinical Interventional Radiologist possible. Throughout my 25-year career at the University of Vermont, I have continuously participated in frequent emergency call duties at a busy Level I Trauma Center, ranging from every other week to every fourth week in frequency. I have introduced or co-introduced innumerable vascular and non-vascular Interventional Radiology procedures to the state of Vermont, and still perform many neurointerventional, aortic endografting, and peripheral vascular interventions. We serve as the only tertiary care referral center for the entire state of Vermont and much of the Adirondack region of New York state. My electronic teaching collection, consisting of around 3,000 interesting procedures that I have personally performed, is a testament to my clinical Interventional Radiology experience. I estimate that I have placed more than 800 IVCFs and have retrieved many IVCFs since the advent of optional IVCFs in the U.S., around 15 years ago.

I also received a Master of Science degree from the Ohio State University Graduate School in 1990, with a concentration in radiation physics and radiobiology. I am a Fellow of the Society of Interventional Radiology and a Fellow of the American College of Radiology. In addition, I am a member of many medical societies and organizations. I am a diplomat of the American Board of Radiology in Vascular and Interventional Radiology, a subspecialty of Diagnostic Radiology, and hold certificate no. 34386.

Attached to this report as exhibit A is a list of all testimony which I have given in the past four years. Additionally, my curriculum vitae is attached as exhibit B. Finally, attached as exhibit C is a list of material that has either been provided to me or that I have located myself.

Research Interests on IVCFs

I have studied and published research on IVCFs (1-6). Early in my career, before the advent of retrievable IVCFs, I investigated the role of permanent IVCFs in the trauma population. When the first removable IVCF, the Cook Gunther Tulip filter was available in the U.S., I published our experience with the use of this IVCF at a level I Trauma Center. My research interests have included the investigation of various methods for following optional IVCFs clinically, with the intent of increasing the IVCF retrieval rate. In addition, my colleagues and I have studied the maximum procedure fluoroscopy time recommended for simple retrieval techniques before continuing on to advanced techniques for IVCF removal. I have also served on the Data Monitoring and Safety Committee for the RETRIEVE I and RETRIEVE II studies, evaluating the

Crux retrievable IVCF, for Crux Biomedical, Inc., prior to market. I co-founded a multidisciplinary IVC Filter Management Team in 2006. We were honored by our institution in 2010 by winning the Becoming One Team Award of the University of Vermont Medical Center, which was a reflection of institutional recognition of interdepartmental collaboration to improve patient safety through research.

For all of these reasons, I am highly qualified to evaluate and objectively render an opinion on issues relating to the indications, contraindications, complications, and retrieval of IVCFs, as well as the management and follow up strategies of patients with IVCFs.

Types of IVCFs and Experience with IVCFs

Over my career, I have used many types of IVCFs, both permanent and removable. The original IVCF was the the Mobin-Uddin umbrella, developed in 1967 and available for use in 1970. I have treated multiple patients who had this permanent umbrella in place. Dr. Mobin-Uddin was a professor of Surgery at the Ohio State University College of Medicine, where I was a resident in Radiology. During my time at Ohio State, we placed the Kimray-Greenfield IVCF percutaneously, which was a novel approach to the treatment of venous thromboembolism, and completely replaced the Mobin-Uddin umbrella. Also, during this time, the Cook Gianturco-Roehm Bird's Nest IVCF became available. The Greenfield and Bird's Nest IVCFs are still available as permanent IVCFs and are still kept in our inventory as permanent IVCFs. By the time I entered my fellowship, we had several additional IVCF options that we used, including the LGM Venatech and the Bard Simon Nitinol (BSN) IVCFs. The division of Vascular Radiology at Massachusetts General Hospital was pivotal in evaluating the clinical efficacy of the BSN IVCF in the late 1980s and was instrumental in bringing this IVCF to general use. Multiple different versions of the Greenfield IVCF were introduced in the 1990s, which was the most common permanent IVCF used in the U.S. During this time period, insertion rates of IVCFs increased, mainly due to the belief in trauma centers that the multi-trauma population was best served with "prophylactic" IVCFs. We soon started placing several additional IVCFs, including the Cordis Trapease and LGM Venatech LP, which were additional permanent IVCFs. Each IVCF had its role in our inventory. For example, the Cook Bird's Nest was the only IVCF that could be placed in a mega cava, which is a large inferior vena cava, up to 40 mm in diameter. The BSN IVCF was very low profile and could be placed through an arm vein, which might be the only access vein available.

Many European Interventional Radiologists gained a lot of experience, in the 1990s with the first removable IVCF, the Cook Gunther-Tulip IVCF. Beginning in the early 2000s, when the Cook Tulip IVCF first became available in the U.S., we placed many Cook Gunther-Tulip IVCFs for an off label temporary indication in trauma patients, and removed them as soon as possible. One of the problems of the Cook Gunther-Tulip IVCF was that we believed it could only stay in place for about two to three weeks before it needed to be removed or re-positioned, or else it was thought that it would become a permanent IVCF. Because of this, it became very onerous to

bring patients back to the Interventional Radiology suite for an invasive procedure every 21 days just to re-position the Cook Gunther-Tulip IVCF, as many of these patients needed the IVCF to remain in place for many months before removing it. One can imagine the excitement in the U.S., when the Bard Recovery IVCF, with the same conical design and nitinol composition of the predicate BSN IVCF, both well known to Interventional Radiologists, became available. Soon after its release, the Bard Recovery IVCF was FDA cleared as the first and only retrievable IVCF, which could stay in place for a longer period of time before removal. It did not require re-positioning procedures, and could be retrieved or left to stay in place as a permanent IVCF. Soon, reports of retrieval more than one-year post placement appeared, which made the Bard Recovery IVCF a very popular IVCF, since it could stay in place as a permanent IVCF, or be removed percutaneously at a later date. Many patients benefited from the advent of the "optional" Bard Recovery IVCF. These were often placed into patients who could not be protected from life threatening pulmonary embolism with systemic anticoagulation for various reasons. Since IVCFs could now be retrieved relatively easily, if the indication for the IVCF expired, another large increase in the placement of IVCFs occurred in the U.S. in the early to mid 2000s. The Bard Recovery IVCF, and its successors, the G2, G2 Express, and G2X IVCFs became popular retrievable IVCFs in the U.S. Further design improvements resulted in the Bard Eclipse, Meridian, and Denali IVCFs. Soon after the introduction of the Bard Recovery and G2 IVCFs, other IVCF manufactures developed similar conical or alternative retrievable designs, or were already available in clinical practice in Europe, and became available in the U.S. These included the Cook Celect (alternative more retrievable design of the Cook Gunther-Tulip), Argon Option Elite, Cordis Optease, and ALN International, Inc., ALN, and Rafael Medical SafeFlo IVCFs. Later, the Volcano Corporation Crux IVCF became available. Of these retrievable IVCFs, in addition to the Bard IVCFs, we have experience with the Cook Celect, Cordis Optease, and Volcano Crux IVCFs at the University of Vermont Medical Center. The Optease and Crux IVCFs can be retrieved from a femoral vein approach (below), but all of the other optional IVCFs must be retrieved from a jugular or subclavian vein approach (above). Despite all of these other options, we have been very comfortable and satisfied using the Bard family of IVCFs as our most popular optional IVCF over the past 13 years.

Standard of Care of IVCF Retrieval

It is well established that many indwelling IVCFs residing within patients are no longer needed and the indication for continued IVC filtration is time limited. These filters can be removed, if and when medically indicated (7-10). Although IVCFs are life saving devices, and have well documented indications, the consensus in the medical community is that a risk to benefit analysis of possible removal should be conducted once the indication for the IVCF has passed. This recommendation has been made due to the fact that a long term indwelling IVCF carries a low risk of complication (7). These complications include thrombosis, migration, perforation, and fracture, with or without embolization of fragments (11). It is also well known that an optional IVCF, such as the Bard family of retrievable filters, is most easily removed within the first year after placement. With time, an IVCF can become firmly adhered to the wall of the

inferior vena cava through the process of fibrosis. In addition, some filters can tilt away from the central axis of the inferior vena cava, with the retrieval hook becoming embedded into the fibrosed wall of the inferior vena cava, rendering a subsequent retrieval procedure much more difficult and higher risk to the patient. In these cases, advanced percutaneous techniques to remove an IVCF can be deployed, such as using tip deflecting guidewires, balloon catheters, and endocardial or endobronchial biopsy forceps to free the embedded hook of the IVCF from the inferior vena cava wall. Once the hook is free, the entire IVCF can then be pulled into a large sheath with the aid of a wire loop snare, or biopsy forceps, and then removed from the body. In extreme cases, a fiberoptic laser can be used to break up the IVCF, and then the fragments can be individually removed with a snare or forceps.

Advanced techniques of removing an IVCF may result in traumatic injury to the wall of the inferior vena cava. The long term effect of this trauma is unknown.

During my career as an Interventional Radiologist, including five years as a resident, one year as a fellow, and over 25 years as an attending at the University of Vermont, I have witnessed many changes in the practice of inferior vena caval filtration. Until 1993, the classic indication for an IVCF was a patient with documented venous thromboembolic disease, and at least one other condition, such as a contraindication or complication of systemic anticoagulation. Then, the indications for IVCFs were broadened, and many IVCFs were placed into patients without documented venous thromboembolic disease (2). These were mainly patients with a high risk of developing life threatening venous thromboembolic disease, such as victims of multiple trauma who could not be safely treated with anticoagulation to prevent pulmonary embolism. The number of IVCFs placed nationally soared in the mid to late 1990s, mainly due to a newly recognized population (trauma and surgical patients) that many thought could benefit from receiving an IVCF on a prophylactic basis. Then, when the retrievable (optional) IVCFs became available in the early 2000s, another dramatic increase in the number of IVFCs placed nationally occurred (12-16). This was mainly due to increased enthusiasm by Interventional Radiologists and Surgeons, as these new IVCFs could be retrieved when no longer needed. As long term complications of IVCFs were increasingly recognized, the number of IVCF placements has decreased over the past 10 years in patients that did not meet the classic strict indications for an IVCF.

Early in the experience with optional IVCFs, low IVCF retrieval rates of between 10 and 33% were reported (17-20). The reason for this was multifactorial. Many institutions did not have a standard IVCF follow up protocol in place, and therefore many patients with an optional IVCF were never clinically evaluated for the feasibility of IVCF removal. Either the implanting physician, primary care provider, or hematology specialist could have provided this follow up, but some patients were lost to follow up. Other patients were non compliant, and despite the best efforts of the implanting or clinical provider team to re-evaluate these patients in follow up, they were unsuccessful. This may have been due to extenuating circumstances, such as financial hardship, or apathy and lack of personal responsibility on behalf of the patient. Finally, many patients had an ongoing indication for inferior vena caval filtration, and therefore their optional IVCF became permanent.

After a patient receives a retrievable (optional) IVCF, the decision to leave it in place as a permanent IVCF versus removing it, is an individual decision that is multifactorial. There is not a "one size fits all" approach to making a decision about whether or not to remove an IVCF, nor would such an approach be beneficial to the patient. Patients should be "clinically reassessed periodically" to determine if and when their IVCF should be removed (7). Even if an IVCF is no longer indicated, a decision may be made, in the best interest of the patient, to leave the IVCF in place as a permanent IVCF based on anatomic factors (chronically occluded inferior vena cava, no patent route for access to the IVCF for retrieval, thromboembolus or acute thrombus within the IVCF or inferior vena cava, etc.), life expectancy of less than one year, inability to attain adequate systemic anticoagulation (either due to allergic reactions to the medications, inadequate metabolism of the anticoagulant medications, or noncompliance with taking the anticoagulant medications), or advanced age. The initial decision on whether or not to remove an IVCF is individualized for each patient and made solely on clinical parameters, and no imaging study will have any bearing on this decision. The U.S. FDA recommends that a retrievable IVCF be removed, once protection from pulmonary embolism is no longer needed. The FDA also encourages physicians involved in the follow up of IVCF recipients to consider the risks and benefits of filter removal for each patient. If a patient has a retrievable IVCF that should be removed based on his or her individual risk to benefit profile, the patient should be referred for IVCF removal when feasible and clinically indicated (9, 10). In addition, imaging should not be entertained until after the initial decision to remove an IVCF has been made, not before. Once the decision to remove an IVCF has been made, then an appropriate imaging study could be performed to ensure that the removal procedure is feasible, namely that the inferior vena cava and IVCF are patent.

In many institutions, following the placement of an optional IVCF by an interventionalist (Interventional Radiologist or Vascular Surgeon), the patient becomes lost to follow up with respect to his or her IVCF. The most common causes of IVCF non-retrieval are physician oversight, inattention to patient management, and patient non compliance (21, 22). Essentially, these patients are not being followed up appropriately (23). In one study, IVCF patients with a documented management plan had a retrieval attempt in 77.3%, but those without a documented plan had a retrieval attempt in 11.1% (24). If the implanting physician (interventionalist) does not assume ownership of the patient, then the responsibilities of the IVCF follow up will fall onto the primary care physician or clinician taking care of the patient, who may not have focused on the fact that an optional IVCF was placed or who may not be focused on follow-up of the IVCF. A failure of communication between the interventionalist or the physician who ordered the IVCF placement and the primary care physician is not uncommon. The FDA communications of 2010 and 2014 were largely an acknowledgment of this disconnect and communication failure and was an attempt to provide guidance for the interventionalist and/or clinician assuming care for the patient to assess the patient for possible IVCF removal, once protection from pulmonary embolism is no longer needed or when feasible and clinically indicated (9, 10).

Beginning at least with the Bard G2 filter, the *Instructions for Use* (IFU) accompanying each IVCF included this statement: "**Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device."** The IFU also referred the implanting physician to three different guidelines and standards published in the Journal of Vascular and Interventional Radiology relating to clinical follow up IVCFs (8).

The FDA has developed a National System for Health Technology (NEST) which strives to build an "effective national medical device surveillance system" (25, 26). Clinical follow up and surveillance of a medical device is not a new phenomenon and is not specific to IVCFs. Other implantable devices require varying degrees of clinical follow up. For example, a vascular stent may require very little follow up, other than periodic duplex ultrasound imaging to detect for restenosis and to reconcile antiplatelet medications. A total hip replacement will require intensive rehabilitation and clinical follow up in the short term, but essentially none in the long term. A cardiac pacemaker will require close monitoring for life, as rate changes and other parameters may need to be adjusted, and batteries need to be changed (27). New devices have often participated in post market surveillance programs.

Benefits of Inferior Vena Caval Filtration

The mainstay treatment of acute pulmonary embolism and deep venous thrombosis is systemic anticoagulation (28, 29). Immediate treatment with intravenous heparin has been shown to improve survival for patients with pulmonary embolism, in addition to decreasing the rate of recurrent venous thromboembolism (30-33). However, not all patients with acute pulmonary embolism or deep venous thrombosis can be safely treated with anticoagulation, either due to a contraindication, complication, such as life threatening bleeding, or failure of anticoagulation. Fortunately, it is widely accepted that these patients would benefit from the placement of an IVCF, since IVCFs are designed to prevent pulmonary embolism. IVCFs have been shown to decrease pulmonary embolism in the PREPIC trial, even showing an additional protective effect for a certain period of time in patients receiving permanent IVCFs who are already anticoagulated (34, 35). The PREPIC-2 trial attempted to evaluate the efficacy and safety of retrievable IVCFs by randomizing a very complex group of nearly 400 higher risk patients with pulmonary embolism and deep venous or superficial vein thrombosis and at least one other criterion, such as age greater than 75, cancer, stroke, paralysis, etc. Again, one arm received an IVCF in addition to anticoagulation and the other received only anticoagulation. No difference was observed between the two groups with respect to death from any cause at three and six months. The IVCF group experienced more recurrent pulmonary embolism (36). Neither PREPIC or PREPIC-2 studies reproduced the generally accepted indications for an IVCF, namely that an IVCF should be placed in patients that cannot receive anticoagulation for pulmonary embolism or deep venous thrombosis. A prospective randomized controlled trial comparing IVCFs to no treatment, or to any other treatment, in the prevention of pulmonary embolism has

never been performed, since it would be considered unethical to do so. A randomized controlled trial comparing IVCFs placed for pulmonary embolism to no treatment would subject the patients in the no treatment arm to a 30% mortality rate from recurrent pulmonary embolism, which would be untenable. Comparing IVCFs without anticoagulation to anticoagulation alone would also be a tenuous study, since we already know that anticoagulation is a very effective treatment in preventing potentially lethal recurrent pulmonary embolism. The prevailing medical opinion (standard of care) is that IVCFs are advantageous in preventing pulmonary embolism compared to no treatment and that patients with an acute pulmonary embolism or venous thromboembolic disease that cannot receive systemic anticoagulation, should receive an IVCF.

Although there are no randomized controlled trials showing the efficacy of IVCFs in preventing recurrent or acute pulmonary embolism compared to no treatment in patients with venous thromboembolic disease (pulmonary embolism or deep venous thrombosis), many retrospective cohort, cross-sectional, and case control studies have been performed which do show a benefit of IVCFs in preventing pulmonary embolism. A retrospective database study of the impact of IVCFs on the in-hospital case fatality rate from pulmonary embolism looked at different patient categories in an attempt to risk stratify and determine which subset of patients benefited from the placement of an IVCF (37). All patients had pulmonary embolism. This study found that the fatality rate was lower for patients that received an IVCF than those that did not. The greatest benefit of receiving an IVCF was for patients that received thrombolytic therapy and for unstable patients. Proctor and Greenfield evaluated patients with pulmonary embolism and showed a dramatic reduction of in-hospital case fatality rate in the patients that received an IVCF, from 44% to 18% (38). In addition, the Japanese Society of Pulmonary Embolism Research registry demonstrated a reduced 30-day case fatality rate from pulmonary embolism in the patients that received an IVCF (39). Another study of patients with pulmonary embolism who received an IVCF at Veterans Affairs Medical Centers showed a reduction of the all-cause case fatality rate (40). Other sub-groups of patients that appear to benefit from placement of an IVCF are stable patients with pulmonary embolism and solid malignant tumors who are older than age 30 years (41) and clinically unstable adults with pulmonary embolism (42). In a prospective cohort study of patients with acute venous thromboembolism, 344 patients treated with an IVCF (with or without anticoagulation) were matched with 344 patients only treated with anticoagulation. The risk adjusted pulmonary embolism mortality rate was lower for the IVCF patients (43).

Overall, pulmonary embolism accounts for 50,000 to 200,000 deaths annually (44-46). It is a significant public health problem and accounts for a large percentage (10 to 11%) of in-patient (in hospital) deaths, based on autopsy studies (47, 48). It is well known that a much larger number of patients suffer from acute deep venous thrombosis, than acute pulmonary embolism. There is no way to predict which patients with deep venous thrombosis will eventually experience a pulmonary embolism. These patients are at an increased risk of developing a fatal pulmonary embolism, yet not all of these patients can be treated with the first line therapy, systemic anticoagulation. Taken collectively, the number of patients successfully treated for pulmonary embolism and deep venous thrombosis by an IVCF is large.

Therefore, IVCFs have prevented many deaths, which would have been attributed to acute pulmonary embolism and recurrent pulmonary embolism. IVCFs are truly life saving devices.

There is no question that IVCFs save lives in patients with a proper indication for an IVCF. The problem we face is that many patients have received IVCFs for non classical indications (28, 49), due to physician preferences. As with any device, if its clinical utility has passed, the device will only act as a foreign body and is often removed. Most experts believe that patients who receive an IVCF should be observed carefully and systematically and followed for IVCF retrieval, if appropriate (50).

Qualities of Different Bard IVCFs

Not all Bard IVCFs are equal. The BSN IVCF has been available for more than 25 years as a permanent low profile IVCF. It is so small that one version of this IVCF can be inserted through a peripheral arm vein. A long term evaluation of 114 patients with the BSN IVCF showed that this filter had a significant complication rate, including a 95% IVC perforation (76% grade 3 perforations) rate, a 16% fracture rate, and a 63% eccentric position rate (51). After the Bard Recovery and subsequent G2 IVCFs became available, the number of IVCF insertions increased, clinical follow up was recommended, and protocols were slowly adopted. Initially, the Bard Recovery Cone was required for retrieval, as the Recovery and G2 IVCFs did not have a retrieval hook. With the advent of the G2 Express IVCF, a retrieval hook was adopted on the nose of the IVCF and all subsequent Bard IVCFs were designed to be retrieved using a generic loop snare, making the Recovery Cone obsolete. The subsequent Bard IVCFs, with their broader shoulders, more robust foot anchors, electropolished finish, etc., have continually improved on the original Recovery IVCF design.

Despite the fact that the only long term evaluation of the BSN IVCF showed high complication rates, this information is not widely known by the medical and Interventional Radiology communities. This may be due in part to the fact that these IVCFs were non retrievable, and therefore they were not subjected to the intensive imaging scrutiny of optional IVCFs that occurs during the retrieval procedure. Therefore, less complications were reported since less imaging follow up was available. All permanent IVCFs have associated complications, and some of these have been shown to be much higher than many interventionalists realize.

No medical device is perfect or flawless and the ideal IVCF does not exist (11). The evolutionary process in IVCF design exhibited by Bard strives to make the best IVCF possible, with the highest degree of efficacy and the lowest degree of complications.

Similar to the evolution of all medical devices, incremental design improvements were made to subsequent generations of Bard optional IVCFs, so that the latest version, the Bard Denali IVCF, is a much different IVCF than the nascent Bard Recovery IVCF. The implication that this disparate group of IVCFs all have the same risk profile is not supported in the medical literature. The length of time that an optional IVCF is in place within the inferior vena cava does make a

difference with respect to risk and complexity of the retrieval procedure. I believe many interventionalists would recommend retrieving a later generation of an optional IVCF, such as the Bard Denali, if removal is indicated, despite the IVCF residing in place for more than two or three years. However, since most Bard Recovery IVCFs have now been in place for over 10 years, fewer recommendations for removal of these can be made, since very aggressive techniques usually need to be performed to remove a fibrosed IVCF in place for over 10 years. In general, the risk to benefit ratio often does not support the removal of a Bard Recovery IVCF in the year 2017.

The IFU of the Bard Denali IVCF is replete with possible risks and complications with the use of the IVCF (52). It states the following:

1. *Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.*
2. *Movement, migration or tilt are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration. Migration may be caused by placement of the filter in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.*

In addition, the Bard Denali IFU contains an extensive list of potential complications and states:

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- *Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.*
- *Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.*
- *Detachment of components.*
- *Perforation or other acute or chronic damage of the IVC wall*
- *Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.*

- *Deep vein thrombosis*
- *Caval thrombosis/occlusion*
- *Extravasation of contrast material at time of venacavogram*
- *Air embolism*
- *Hematoma or nerve injury at the puncture site or subsequent retrieval site*
- *Hemorrhage*
- *Restriction of blood flow*
- *Occlusion of small vessels*
- *Distal embolization*
- *Infection*
- *Intimal tear*
- *Stenosis at implant site*
- *Failure of filter expansion/incomplete expansion*
- *Insertion site thrombosis*
- *Filter malposition*
- *Vessel injury*
- *Arteriovenous fistula*
- *Back or abdominal pain*
- *Filter tilt*
- *Hemothorax*
- *Organ injury*
- *Phlegmasia cerulea dolens*
- *Pneumothorax*
- *Postphlebitic syndrome*
- *Stroke*
- *Thrombophlebitis*
- *Venous ulceration*
- *Blood loss*
- *Guidewire entrapment*
- *Pain*

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Interestingly, this list of possible complications was present in the IFU of all Bard IVCFs since the Bard G2, although the single addition of "detachment of components" was added to the Bard Eclipse and subsequent Bard IVCFs. However, this concept was implicit in the Bard G2 IFU paragraph on filter fractures, as the IFU stated that "there have been reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques" (8, 52). In addition, all of these risks

and complications attributed to Bard IVCFs are also applicable to all brands of IVCFs, which is supported by the ACR/SIR/SPR Guidelines (7).

Literature of IVCF Follow-up Programs

The more recent medical literature is replete with examples of systematic protocols and methods to follow-up patients with optional IVCFs, so that those patients with an indication for IVCF removal are clinically assessed for IVCF retrieval (6, 53-63). These 12 studies invariably show increased optional IVCF removal rates when a dedicated program to follow-up IVCF patients is implemented. These institutional programs use various techniques to track patients with an optional IVCF, so that they are offered the opportunity for IVCF removal as soon as they no longer have a need for their IVCF. The objective of these protocols is to provide timely clinical follow-up and to assess the appropriate patients on an individual basis regarding their risk to benefit ratio with respect to IVCF removal. As an example of a method, at our institution, the implanting physician is obligated to check a box in the electronic medical record post procedure order set, which automatically generates a consult to the medical hematology and thrombosis clinic for an appointment three-months post IVCF placement. We also have an option to check another order which generates a consult to the interventional radiology clinic at three-months post placement, to discuss the procedural issues relating to IVCF retrieval. To ensure that these appointments are scheduled, our interventional radiology nurses also place a telephone call or send a facsimile consult request to the respective clinics.

The degree of homogeneity of the population assessed will largely determine the optimal IVCF retrieval rate achievable. For example, retrieval rates for trauma populations, which are often younger and healthier than general medicine populations, are often the highest when subjected to a systematic follow-up program. Retrieval rates between 70 and 95% have been published in trauma series (53, 55, 62). In heterogeneous populations most often encountered by interventional radiologists, the published retrieval rates are a somewhat lower when subjecting patients to a rigorous follow-up protocol, ranging between 45 and 83.5% (6, 54, 56). The general medicine and non trauma patient populations are often older with multiple problems, such as cancer and debilitating chronic diseases. A greater percentage of these patients will have a continued indication for inferior vena cava filtration, and therefore their IVCFs are more likely to become permanent.

Critique of the Use of Imaging for Monitoring of Patients with Retrievable IVCFs

The relief proposed by the proposed class representatives consists of the establishment of a "(1) notice campaign to all Class members informing them of the availability and necessity of the medical motoring [*sic*] protocol and (2) a "catheter venography" to be performed on every Class member who still has a Bard IVC filter installed by an interventional radiologist who will then consult with the Class member's physician within 60 days to determine if retrieval is

clinically necessary and, if so, to provide the physician with necessary information regarding how much force to exert in removing the Bard IVC filter." The definition of medical monitoring is vague. The relief implies that this includes medical imaging, but this is not supported by the medical literature, the standards of the pertinent medical societies, and the *Instructions For Use* manual supplied with each Bard IVCF, beginning at least with the second generation of optional Bard IVCFs, the G2 (7, 8). Most practitioners would agree with the widely respected authoritative document on IVCFs, the 2016 Revised *ACR-SIR-SPR Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism*, which states that "when a retrievable filter is placed, the patient should be **clinically reassessed periodically** to weigh the benefits of continued filtration (need for PE prophylaxis) against the associated risks (eg. recurrent deep venous thrombosis [DVT], IVC thrombosis, symptomatic penetration, or mechanical failure) and uncertainties (given limited data on long-term mechanical stability and integrity of some devices)" (7).

Medical imaging of the IVCF, other than determining whether or not the inferior vena cava and indwelling IVCF are patent and free of thrombus, has no bearing on whether or not the IVCF should be removed. This is a clinical decision that makes a specific determination of whether or not there is an ongoing indication for inferior vena cava filtration. It is usually based on whether or not there is an ongoing need for pulmonary embolism prophylaxis, which is often limited to three to six months following the diagnosis of an acute lower extremity deep venous thrombosis or a pulmonary embolism, and whether or not the patient can be treated with systemic anticoagulation. These two factors are independent of the state of the indwelling IVCF. In addition, a catheter inferior vena cavogram, or any imaging study of the inferior vena cava and IVCF, such as a CT scan, are "snap shot" investigations, which do not predict what may happen to the inferior vena cava or IVCF in the near or remote future. Investigation of the IVCF should not occur prior to making an individualized clinical decision. The pertinent question that the physician evaluating a patient with an optional IVCF must make is whether or not the IVCF should be removed.

Once the clinical benefit/risk has been determined to favor removing the IVCF, then imaging, such as a non invasive and low cost duplex ultrasound could be performed to ensure patency of the IVC and IVCF. During the potential retrieval procedure, an inferior vena cavogram must be performed, and therefore, any inferior vena cavogram obtained prior to this procedure would be superfluous, unnecessary, and potentially high risk to the patient. Only a patient's provider, such as the implanting physician, primary care physician, or specialty consultant seeing and evaluating the patient in follow up, can understand all of the variables and individualized clinical issues of his or her patient before making a decision of whether or not to remove an IVCF. If there is a clinical indication for IVCF removal, no condition of the IVCF would make removal contraindicated, other than inferior vena caval or IVCF thrombosis. Once a clinical decision for IVCF removal is made, the interventionalist needs to make a decision on a case by case basis regarding further work-up, including imaging, prior to the removal procedure.

Many institutions already have protocols in place which clinically re-assess patients with an IVCF. Imaging, such as an inferior vena cavogram or a CT scan, should not be part of a follow up

strategy. This would be placing the "cart before the horse." As an example, we have published our IVCF follow up protocol, which does not include medical imaging (6). To my knowledge, no appropriate medical society or consensus group has recommended medical imaging as a specific component of the recommended follow up protocol. The University of Vermont Medical Center IVCF clinical follow up flow sheet is attached as appendix 1, and does not include imaging prior to deciding whether or not to remove an IVCF.

There are many reasons why an invasive procedure, such as a catheter inferior vena cavogram should not be performed as part of a "surveillance" or "medical monitoring" protocol, as requested in the Class Action Complaint. First, it is unnecessary and immaterial to making a clinical decision of whether or not to remove an indwelling IVCF, as described above. In essence, there is no medical indication for an inferior vena cavogram. Second, an invasive catheter inferior vena cavogram is associated with real risks to the patient. Iodinated contrast media is nephrotoxic in patients with underlying renal insufficiency. Some patients with IVCFs have renal insufficiency, and would be placed at risk of further kidney function decline, possibly resulting in the need for hemodialysis. Third, there is the unpredictable risk of a patient developing an adverse (similar to an allergy) reaction to iodinated contrast media, ranging in minor symptoms such as hives, to moderate symptoms such as laryngeal edema and difficulty breathing, to a major reaction, such as cardiovascular collapse and sudden death. Fourth, since a catheter is placed percutaneously into the femoral or jugular vein after a needle puncture, there are attendant risks with this technique, such as hematoma, hemorrhage, nerve and blood vessel injury (arteriovenous fistula and pseudoaneurysm), and pneumothorax (lung puncture) if a jugular approach is used. Fifth, although modern radiology imaging chains have dramatically decreased radiation exposure over time, the radiation risk (stochastic and deterministic events) with this procedure over a large population group is not inconsequential. Sixth, most Interventional Radiologists recommend that a catheter inferior vena cavogram be performed with the use of intravenous moderate (conscious) sedation, which poses another risk to the patient. Seventh, a catheter inferior vena cavogram is expensive, and would be required to be performed during the IVCF removal procedure, potentially duplicating imaging costs. Eighth, contrary to what is stated in the Class Action Complaint, an inferior vena cavogram is not predictive of how much "force" the retrieving physician needs to exert to remove a Bard IVCF. This determination is based on experience of the interventionalist and a practical trial and error technique, which resides within each interventionalist's comfort zone, and has no relationship to pre-removal imaging whatsoever. Ninth, a catheter inferior vena cavogram often has limited diagnostic utility in obese patients. This is because the body habitus of obese patients creates an enormous amount of scatter radiation, which blurs the image created on the radiation receptors. An obese patient also requires much greater exposure parameters, causing a bigger radiation dose to the patient and the operators, which also detracts from the image quality through motion artifact. Finally, some patients with an IVCF are not amenable to a conventional inferior vena cavogram. The inferior vena cava and the iliac veins may be chronically occluded. In this situation, a catheter cannot be placed into the lower inferior vena cava due to these chronic occlusions, precluding an inferior vena cavogram obtained from a femoral vein approach. In addition, the chronically occluded venous structures will not opacify with iodinated contrast media, and therefore will not be visible on an inferior vena cavogram from

the femoral vein approach. Often, the patients with a chronically occluded inferior vena cava could receive a catheter inferior vena cavogram from a jugular (neck) vein approach. However, the jugular vein approach presents another set of additional risks, including the risks of a pneumothorax and neck hematoma. For all of these reasons, a catheter inferior vena cavogram, as proposed as part of the "medical monitoring protocol" of the plaintiff class representatives is a very poor decision and possibly harmful procedure, with no benefit.

A single non contrast enhanced computed tomography (CT) scan of the abdomen and pelvis has also been proposed as an effective medical monitoring tool for patients with a Bard optional IVCF. There are many reasons why this proposal is not a good idea, and potentially harmful. As in the case of a catheter inferior vena cavogram, a single CT scan is a mere "snap shot" in time of the condition of an IVCF, and does not predict a future complication. Any symptomatic patient with an IVCF in place will most likely have a medical indication for a contrast enhanced CT scan of the abdomen and pelvis, as the risk to benefit ratio favors interrogation with this imaging technique. However, in an asymptomatic patient with an IVCF, the status of an IVCF has no bearing on whether or not it should be removed, as that decision is based on clinical parameters, including the risk to benefit ratio for each individual patient. Therefore, imaging does not contribute to the clinical decision on whether or not to remove an IVCF. Imaging, such as a contrast enhanced CT scan, or a duplex ultrasound examination combined with plain film radiography, may be warranted after an individualized decision is made to remove an IVCF. For example, if a patient with an optional IVCF no longer has a contraindication to anticoagulation and is otherwise ready to have his or her IVCF removed, an interventionalist may decide, on an individual patient basis, whether or not a duplex ultrasound or a contrast enhanced CT scan of the inferior vena cava might be performed to check for thrombus (clot) within the inferior vena cava or the IVCF. If clot is seen, then the IVCF will not be removed for a designated amount of time, until after the clot has disappeared. This clot could be actively treated with transcatheter thrombolysis, but is more often treated with systemic anticoagulation for two to four weeks, which will allow the patient's natural fibrinolytic pathway to resolve the clot. After a follow-up imaging study shows resolution of the clot, then the IVCF will be scheduled to be removed. Major limitations of a non contrast CT scan of the abdomen and pelvis include the inability to diagnose inferior vena cava thrombosis (occlusion) and/or a significant thromboembolus within the IVCF, which are contraindications for IVCF removal. If a patient with an IVCF has a symptom at any time, such as abdominal pain, then a contrast enhanced CT scan may be warranted, not a non contrast enhanced CT scan.

There are significant risks to exposing a large population to a CT scan of the abdomen and pelvis, due to the ionizing radiation inherent in a CT scan, whether it be a non contrast enhanced or contrast enhanced CT scan. Ionizing radiation causes cellular changes that can result in cancer. The 2009 National Council on Radiation Protection and Measurements, Report No. 160 — Ionizing Radiation Exposure of the Population of the United States — showed that medical exposure to patients is one of the largest sources of radiation exposure to Americans, nearly equaling the exposure from background sources (64). Computed tomography (CT) is the largest source of medical radiation exposure (65). For comparison purposes, the effective radiation dose from a mammogram is 0.4 mSv, whereas the dose from a non contrast CT scan

of the abdomen and pelvis is much higher at 10 mSv, which is the equivalent dose obtained from 200 chest radiographs (x-rays) or 1,500 dental x-rays (66). Based on extrapolated data from historical nuclear events, the National Cancer Institute and others have estimated that the fatal cancer risk from one typical CT scan is 1:2,000 (67). Studies have estimated that CT scans will cause up to 2 percent of future cancers, which will result in about 29,000 cases and 15,000 deaths annually (68-70). These alarming statistics prompted the American College of Radiology to promote the "Image Wisely" and "Image Gently" campaigns, which seek to educate patients and doctors about unnecessary tests, such as a CT scan for headaches or back pain, and the risks associated with them, obtained for very little benefit. If a non-enhanced CT scan was obtained on every patient that received a Bard Recovery IVCF (estimated to be 32,000 patients)(71) and a G2 or G2X IVCF (estimated to be 180,000 patients) (72) for a total of 212,000 patients, then the CT scans alone would be responsible for causing 106 cancer deaths. Of course, some of these patients are no longer alive, so the total number of living patients with a Bard Recovery or G2 IVCF may be less then 212,000. This estimate does not include the innumerable non fatal cancers caused by the ionizing radiation of the CT scan, nor does this estimate include the thousands of patients that have received the Bard Eclipse, Meridian, and Denali IVCFs, who would also be subjected to this radiation exposure under the proposed regimen of non contrast enhanced CT scans for all Bard IVCF recipients.

Another serious problem with over-utilization of medical imaging tests, such as CT scans, is the risk of overdiagnosis, otherwise known as the detection of the "incidentaloma." 37% of patients that have received whole-body CT scans have abnormal findings that may need further evaluation (73). This often forces the clinician to pursue even more imaging or invasive procedures, such as biopsies and drainage procedures, for further clarification. Most of these abnormal findings are totally benign, and of no consequence. However, the invasive procedures necessary to make this determination have associated risks, which may cause significant morbidity and occasional mortality. Overdiagnosis also drives up health-care costs.

Critique of Plaintiff Expert Reports

Expert Report of Dr. Hertz

I have reviewed the Expert Report of Dr. Hertz. It is notable that no authoritative society or organization has specifically recommended imaging as part of a surveillance or medical monitoring program regarding IVCFs. Dr. Hertz has proposed that every patient with a Bard IVCF, except those with the Bard Denali IVCF, receive a single non contrast enhanced abdomen and pelvic CT scan. This ill-advised concept has been refuted elsewhere in this report. It is not clear why Dr. Hertz wants to exclude patients with the Bard Denali IVCF.

Although Dr. Hertz has cited low retrieval rates for optional IVCFs, many studies have been published showing retrieval rates between 45 and 95%, when associated with a systematic follow up plan. Many IVCF protocols and follow up plans have been published and described.

Those institutions which have no IVCF follow up plan in place have not been following the recommendations of multiple societies, the FDA, and every IFU contained within the box of each Bard IVCF, beginning with the G2. At my institution, we have been following a strict IVCF follow up protocol for over 10 years.

In paragraph #35, Dr. Hertz attempts to explain a complicated rationale behind his suggestion to begin monitoring with a non contrast CT scan at three-months post placement. I disagree with his recommendation and his reasoning behind beginning follow-up at the three-month juncture. The rationale behind clinically assessing most patients with an IVCF at three-months post placement is straightforward. In most cases, the IVCF has been placed as a substitute for systemic anticoagulation in the setting of acute venous thromboembolic disease, for protection against pulmonary embolism. The mainstay treatment for venous thromboembolism, systemic anticoagulation, is often discontinued after three months (possibly six months for pulmonary embolism). Therefore, the substitute for systemic anticoagulation, the IVCF, can also be discontinued (removed) after three months. This is the time when many patients no longer have an ongoing indication for inferior vena cava filtration, and many IVCF patients will become candidates for removal of their IVCF at this three-month juncture.

As Dr. Hertz mentions in paragraph #38, patients with “severe medical conditions” may not have their IVCFs removed, because the risk of the retrieval procedure cannot be justified. In my experience, this group of patients with severe medical problems that receive an IVCF is quite large with an extensive list of co-morbidities. Therefore, there is no rationale for imaging this large group of patients with a CT scan, if their IVCF has been determined to be permanent and they are asymptomatic. For example, a patient with terminal cancer and a life expectancy of less than one year, who most likely received an IVCF for compassionate use purposes, should not be evaluated for IVCF removal for obvious reasons. Another example may be an elderly patient, who should not be evaluated for IVCF removal, since the risk of removing the IVCF most likely would be greater than the risk of leaving it in as a permanent IVF. Finally, a patient with severe lung disease requiring home oxygen therapy and a history of multiple pulmonary embolism episodes, most likely should not be evaluated for IVCF removal, since a recurrent pulmonary embolism would likely be fatal due to poor pulmonary reserve.

In paragraph #42, Dr. Hertz laments the lack of a systematic program or protocol in his local health care system or other area hospitals to conduct follow up or surveillance of patients after placement of an optional IVCF. This may reflect a deficiency of Dr. Hertz’s health care system and the other area hospitals, as the medical community and the physicians implanting optional IVCFs have been extensively notified of the need of these patients to be “clinically reassessed periodically” and be “tracked and receive ‘routine follow up’ subsequent to placement of the device” (7, 8). Indeed, my institution had no difficulty developing and implementing a systematic follow up program more than 10 years ago, which effectively increased our IVCF removal rate from 23 to 45% (6).

In Dr. Hertz’s concluding paragraph #46, he mentions that multiple national and international societies and governmental agencies recommend “monitoring” of patients with an IVCF.

However, he omits that these same societies and agencies do not promote imaging as part of the surveillance or follow up recommendation. Any prudent clinician already has the option of obtaining a CT scan on his or her patient with an IVCF, if medically indicated.

Some authors have advocated imaging as a means to longitudinally follow-up asymptomatic patients with an IVCF in place (74-77). However, most do not, and there is wide disparity among their preferred technique for those that do. To my knowledge, only one study recommends routine imaging as part of the IVCF follow up strategy. Hull and Robertson, at the conclusion of their study of Bard Recovery IVCF complications, have advocated imaging with abdominal CT to screen for perforation, fracture, and migration in patients with a Recovery filter in place, although they do not state whether they recommend the CT with contrast enhancement (74). Rectenwald performs an annual abdominal radiograph, Kaufman gets an abdominal radiograph (plain x-ray) at the one-year follow-up appointment, and Plant does an abdominal radiograph and Doppler ultrasound exam annually (75). Giroux recommends a noncontrast CT scan at 6 months as part of her protocol (76). The most aggressive imaging follow-up strategy proposed is part of the ongoing PRESERVE study (Predicting the Safety and Effectiveness of Inferior Vena Cava Filters), which is a nonrandomized prospective study involving 1,800 IVCF patients at 60 sites, with 6 IVCF manufacturers represented. This is a unique investigation into many different IVCFs, which requires mandated imaging follow-up with an abdominal radiograph at 3 months and contrast enhanced CT scans at 12 and 24 months (77). Of note, the PRESERVE study is designed to evaluate the overall safety and efficacy of many different types of IVCFs in real world conditions, not just Bard IVCFs, and is not an evaluation of follow-up strategies or imaging protocols.

Expert Report of Dr. Eisenberg

I have read Dr. Eisenberg's report. He questions the clinical efficacy of IVCFs and cites the PREPIC and PREPIC II studies in paragraphs 214, 215, and 216 as evidence that IVCFs do not reduce mortality (34-36). I strongly disagree with this interpretation of the data and believe that IVCFs do work and do reduce mortality. My major criticism with the PREPIC and PREPIC II studies is that they did not reproduce real life indications for placement of an IVCF. These studies were not designed to easily show a benefit of IVCFs. We know that systemic anticoagulation is very effective at preventing recurrent pulmonary embolism and at reducing mortality in patients with pulmonary embolism. No study or authority has ever claimed that IVCFs are better at preventing pulmonary embolism than systemic anticoagulation. Therefore, it is not surprising that the addition of an IVCF to an already known excellent therapy, systemic anticoagulation, did not show a mortality benefit. However, many patients cannot receive systemic anticoagulation for a multitude of reasons, or they have failed a treatment course of systemic anticoagulation. The patients randomized to receive a permanent IVCF in the PREPIC studies were all anticoagulated, and many, if not all, would not have received an IVCF based on the indications for an IVCF published by either the 2016 Revised *ACR-SIR-SPR Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention*

of Pulmonary Embolism or the *Bard G2 Filter System, Femoral Vein Approach, Instructions for Use* (7, 8). It is in the patients who cannot be anticoagulated, that IVCFs are effective in saving lives by providing protection against recurrent pulmonary embolism. A randomized controlled trial of comparing IVCFs to anticoagulation alone or to no therapy may be unethical, as we already know that anticoagulation is very effective in reducing the mortality rate of pulmonary embolism, since such studies would be denying one group of patients to an already known life saving therapy.

In paragraph 195, Dr. Eisenberg describes a case of the original Bard Recovery IVCF migrating to the heart and causing the death of the patient. He then states that no similar cases have been reported with the predicate Bard Simon Nitinol IVCF. However, several years after the availability of the Bard Simon Nitinol IVCF, two cases of migration to the chest, one that transited the heart and ended up in the pulmonary artery, and the other to the heart, were published (78).

Dr. Eisenberg attributes several opinions to Dr. Betensky in paragraph 111. They omit the fact that real world follow-up (outside of research studies) was dramatically increased with optional IVCFs, compared to permanent IVCFs. As an Interventional Radiologist, I can attest to the fact that many patients with permanent IVCFs were not followed, since we never made any effort to track these patients and look for asymptomatic complications such as perforation, fracture, tilt, and migration. With the advent of optional IVCFs, patients began to be tracked. In those patients whose IVCFs were retrieved, intensive digital fluoroscopic and angiographic imaging occurred during IVCF retrieval attempts, providing a new opportunity to evaluate asymptomatic IVCFs. This phenomenon did not occur with permanent (non optional) IVCFs. This pattern could have contributed to the larger number of IVCF complications submitted voluntarily to the MAUDE database during this time-frame of the Bard Recovery and G2 IVCFs. No permanent IVCF was clinically investigated and imaged, on a global scale, to the same degree as the optional IVCFs. Once complications of optional IVCFs were found and widely publicized, Interventional Radiologists began looking more closely for these complications in their own patients, which resulted in more submissions to the MAUDE database and the desire to be the "first" to publish complications of the new IVCFs. Therefore, some element of the "notoriety effect" did occur, contrary to the opinion of Drs. Betensky and Eisenberg. Finally, confounding variables and channeling bias did occur with the bariatric population. Permanent IVCFs with the prophylactic indication were not placed to any significant degree into bariatric patients. However, many bariatric surgeons believed that an optional IVCF was a good solution to the high rate of perioperative pulmonary embolism deaths in their patient population, since the IVCF could be retrieved once their patient became ambulatory and free of pulmonary embolism risk. As we all know, bariatric patients are at a higher risk of many complications due to their morbid obesity, such as post operative infections, cardiovascular disease, and thromboembolic disease, and therefore will be associated with a higher morbidity and mortality than non-obese patients.

Expert Report of Dr. Bates

I have read the Expert Report of Dr. Bates. I believe that he may be confusing medical screening with the one-time imaging test associated with the "medical monitoring" proposal for all patients with a Bard optional IVCF. Since medical imaging is a "snap shot" of the area of interest at a point in time, it must be repeated periodically over time to be considered a screening test for a disease or abnormality that is acquired. A one-time CT scan to detect acquired abnormalities of an optional IVCF does not meet this criterion and should not be confused with a screening test. An annual CT scan of the abdomen and pelvis would be a very aggressive strategy to detect an acquired abnormality with the IVCF. For example, another medical imaging screening test, mammography, must be performed annually or every two years to detect acquired breast cancers. An additional example is colonoscopy, which is usually performed every five to 10 years to detect polyps and colon cancers.

Dr. Bates discusses the "defined population" on page 7, but no identifying data base of patients with Bard optional IVCFs exists, to my knowledge. These patients will be very difficult to identify and contact for any type of follow up program, if all of the implanting institutions have not kept satisfactory records over a long period of time.

Expert Report of Drs. Kinney, Roberts, and Kalva

I have read the expert report of Drs. Kinney, Roberts, and Kalva, who are well-respected Interventional Radiologists. Much of this report revolves around mechanical and biomedical engineering topics, which is beyond my area of expertise. Another large component of this report contains descriptions and analysis of internal Bard documents, such as confidential internal manufacturer communications, in-house bench top and animal research, memoranda, electronic mail, PowerPoint presentations, or product documents which I have not read. I will address these types of materials below. I do believe this expert report tells an important story of how an innovative and nascent retrievable IVCF, with a proven conical design and nitinol composition, has evolved over the past decade. This process might be interpreted as quality improvement, which is a method of technological advancement.

The Bard Recovery IVCF, although not perfect, was cleared by the FDA. My colleagues and I were very pleased that Bard released the Recovery IVCF as soon as they did, because we believed that patients were better served with the Recovery than the preceding Cook Tulip IVCF, when an optional IVCF was indicated. The interventionalists (Interventional Radiologists and Vascular Surgeons) at my institution used the Recovery IVCF from its inception, and its successor, the Bard G2 IVCF, and did not experience the myriad of complications described in the report of Drs. Kinney, Roberts, and Kalva. Of course, we were aware of the early migrations/embolizations (some resulting in death) that were reported to the MAUDE database, but realized that more than a few of these cases were IVCFs placed prophylactically in bariatric patients, prior to surgery. We also understood that a large number of Bard

retrievable IVCFs were being placed, as we were not the only group that replaced the Cook Tulip IVCF with the Bard IVCFs.

I have already discussed many of the clinical studies referenced in # 184-196. Of note, in the Oliva study cited in #185, in 51 patients with G2 IVCFs and a mean dwell time of 53.4 days, they found no fractures and no cephalad migrations.

As a matter of correction, in #254, I believe Dr. Kalva states that the Bard Recovery was the first removable IVCF available for use in the United States. However, it was the first IVCF that was FDA cleared for removal. The removable Cook Tulip IVCF was available before the Bard Recovery IVCF.

Expert Report of Dr. Vogelzang

I have read the Expert Report of Dr. Vogelzang. I respectfully disagree with Dr. Vogelzang's conclusion in paragraph #39. As stated previously in this report, the only long term follow-up study of the Bard SNF shows multiple higher complication rates associated with it compared to the Bard optional IVCFs, including a fracture rate of 16%, perforation rate of 95%, and eccentric positioning rate of 63% (51).

Dr. Vogelzang is a well-respected academic Interventional Radiologist, and is certainly entitled to his opinion in paragraph #40. However, I disagree with his conclusion that the Bard retrievable IVCFs are not safe and effective, and that the risks of implantation clearly outweigh the benefits. We have had the opposite experience with the Bard family of optional IVCFs. My opinion that the Bard retrievable IVCFs are safe and effective is based on my review of the available literature and my personal experience. I believe that national databases and registries, such as the MAUDE database, are important to gaining a greater understanding of new technologies applied to real world situations, but the information derived from them must be interpreted cautiously. For example, during the first years after the availability of FDA cleared retrievable IVCFs, perhaps the Bard optional IVCFs were one of the most popular optional IVCF placed. Since a certain percentage of these IVCFs received a great deal of scrutiny during retrieval, which never occurred with permanent IVCFs, this might partially explain why the MAUDE database received a proportionally higher number of Bard optional IVCF complications. My division of Interventional Radiology has implanted a large number of Bard optional IVCFs since their availability (greater than 1,000 retrievable IVCFs, mostly representing Bard retrievable IVCFs) and has retrieved more than 300 of them. We are also a tertiary care referral center for IVCF removals, and assess patients with an IVCF placed at other institutions for removal, in addition to performing complicated retrievals. Our formal multidisciplinary IVCF follow-up protocol was conceptualized in 2006 and began in earnest in 2007 (6, appendix 1). From this group of over 300 Bard optional IVCFs imaged carefully during the retrieval procedure, we have encountered only four patients with a limb fracture, which were all asymptomatic. Two of these fractures occurred during the retrieval procedure. We have seen no case of a significant migration and no symptom attributed to the IVCF. Our experience with

the Bard optional IVCFs has been excellent. The Bard optional IVCFs remain our most popular IVCF.

Expert Report of Drs. Garcia and Streiff

I have reviewed the expert report of Drs. Garcia and Streiff. Most of their arguments have already been discussed in this report. I do question their statement on page #6, section (1). It seems that they are leaving open the suggestion that it may be reasonable to avoid placing an IVCF in a patient with pulmonary embolism and a contraindication to anticoagulation, since they believe that the efficacy of an IVCF is unknown. In my opinion, this practice would fall below the standard of care.

Indications for an IVCF: FDA Label versus Society and Guidelines Recommendations

The indications for the Bard optional IVCFs, cleared by the FDA (FDA Label), and stated in the IFU of each IVCF is very narrow: *The IVCF is indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:*

- *Pulmonary thromboembolism when anticoagulants are contraindicated*
- *Failure of anticoagulant therapy for thromboembolic disease*
- *Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced*
- *Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated*

The IVCF may be removed according to the instructions supplied under section labeled: "Optional Procedure for Filter Removal" (8, 52).

The indications for an IVCF by the appropriate Societies, the American College of Radiology, the Society of Interventional Radiology, and the Society of Pediatric Radiology, are much broader than the FDA cleared indications. The Society *indications include, but are not limited to:*

1. *Therapeutic (Documented Thromboembolic Disease)*
    1. *Patients with evidence of pulmonary embolus or DVT involving the IVC, iliac, or femoral-popliteal veins and 1 or more of the following:*
        1. *A high risk of a complication from anticoagulation*
        2. *An absolute or relative contraindication to anticoagulation*
        3. *Failure of anticoagulation*
            i. *Recurrent symptomatic PE despite adequate anticoagulant therapy*
            ii. *Inability to achieve/maintain adequate anticoagulation*
            iii. *Propagation/progression of DVT on therapeutic anticoagulation*

2. *Perioperative patients with a history of prior venous thromboembolism (VTE) for whom anticoagulation must be interrupted*
3. *Massive PE postsurgical or endovascular thrombolysis/thrombectomy with residual deep venous thrombus*
4. *Severe cardiopulmonary disease and DVT (eg, cor pulmonale with pulmonary hypertension)*

2. *Prophylactic (No Current Thromboembolic Disease)*

Because the risk-benefit ratio for use of IVC filters for primary PE prophylaxis in patients without a documented DVT has not been clearly characterized, physicians who place them for this indication are strongly encouraged to monitor the actual outcomes achieved and adjust patient selection practices accordingly. All filters placed for primary PE prophylaxis should be of retrievable type, with a defined follow-up plan to subsequently retrieve them unless clinically contraindicated for retrieval.

1. Patients at high risk of DVT/PE but cannot receive prophylactic anticoagulation due to underlying risk of bleeding. The risk of bleeding may be related to underlying clinical disease (cirrhosis, active gastrointestinal ulcer, systemic coagulopathy, etc). Such conditions include, but not limited to:
a. Severecraniospinalinjuryresultinginprolongedimmobilizationorplegiclimbs

b. Pelvic/long-bone fractures
c. Intra-abdominalmass/hemorrhagecompressingpelvicveinsortheIVC[40]

C. Suprarenal Filter Placement

Suprarenal caval filter placement may be considered when any of the following situations exist in addition to the indications listed above:

1. *Presence of IVC thrombus precluding placement of a filter in the infrarenal IVC*
2. *Filter placement during pregnancy*
3. *Thrombus extending above a previously placed infrarenal filter*
4. *Gonadal vein thrombosis*
5. *Anatomic variants: duplication of the IVC, short length of infrarenal IVC*
6. *Significant extrinsic compression of the infrarenal IVC*
7. *Intrinsic narrowing of the infrarenal IVC*
8. *Patients with an intra-abdominal or pelvic mass who will undergo surgery and in whom operative IVC*

   mobilization is contemplated

D. Filters Placed for Temporary Use and Possible Future Retrieval

The indications for filter placement remain the same as described above, except that the mechanical protection for PE is required for short term due to transient inability to anticoagulate a patient.

The use of retrievable filters should also be considered in pediatric and young adult patients since the long-term effects and durability of permanent IVC filters are not precisely known. Currently, there are no filters specifically designed for use in children. The safety of vena cava filters in children is unknown (7).

In general, the Society indications for IVCF placement, which are universally adopted by the medical community and Interventional Radiologists, specifically treats proximal deep venous thrombosis, without pulmonary embolism, as equivalent to pulmonary embolism. Since the incidence of deep venous thrombosis is higher than the incidence of pulmonary embolism, potentially more patients in practice receive an IVCF for deep venous thrombosis than for pulmonary embolism, which is not included in the FDA Label indications. In addition, an IVCF placed for prophylaxis (no documented venous thromboembolic disease, including pulmonary embolism and deep venous thrombosis), is another indication listed by the Societies, but is not included on the FDA Label indications. These factors should be considered when evaluating the clinical appropriateness of any medical practice of IVCFs.

Hierarchy of Medical Literature

Evidence-based medicine has emerged over the past 30 years or so as an attempt to connect medical decision making with the scientific validity and objectivity of well designed and performed research studies. Many organizations have recommended the application of Levels of Evidence schemes, which essentially rank the various research designs into a hierarchy of scientific legitimacy and epistemology. Some well respected centers which strongly support the use of evidence-based medicine include the U.S. Preventive Services Task Force (USPSTF) and the Oxford Centre for Evidence-based Medicine (CEBM) (79, 80).

A simplified hierarchical list of study designs, in descending order of quality of evidence, is as follows: 1) systematic reviews and meta-analyses of randomized controlled trials (best); 2) triple blind, prospective, randomized, controlled trials; 3) cohort studies; 4) case-control; 5) cross-sectional studies; 6) case series and case reports; 7) expert opinions and editorials; 8) laboratory and and animal studies (worst). Level I evidence would include #1, Level II would include #2, Level III would include #3, #4, and #5, Level IV would include #6, Level V would include #7, and Level VI would include #8.

Unfortunately, there is a dearth of Level I and Level II evidence in the Interventional Radiology literature, because these studies are very expensive, difficult to conduct, and time intensive to perform. Instead, most Interventional Radiologists (including the author of this report) have relied on easier to perform studies, such as case-control and cross-sectional studies, which

certainly introduce some uncertainty when interpreting the findings and conclusions. Specifically, many of the published complication rates for IVCFs are questionable and unreliable, for these very reasons. Although most of these non-Level I and II studies should be performed, the conclusions should be interpreted with caution. This skepticism should be applied equally to the many studies showing high and low complication rates with IVCFs.

Frequently Cited Studies of Increased Bard IVCF Fracture Complications

Although all complications are important, no complication of a retrievable IVCF seems to generate more discussion than a limb fracture. Although most limb fractures remain asymptomatic, they have been associated with embolization to the heart and pulmonary arteries (81).

Two retrospective cross-sectional studies from the same institution evaluated the Bard Recovery and the Bard G2 IVCFs and have been often cited as evidence that these IVCFs have extremely high fracture rates (82, 83). However, the design used in both of these studies is weak, particularly when attempting to define a five-year fracture rate. Both studies used similar methodology which lacked systematic and controlled follow-up based on looking up random imaging in a retrospective fashion. The Tam study of the Recovery IVCF concluded that the Kaplan-Meier survival estimates of the Recovery IVCF fracture rate was 40% at five years. They only diagnosed 20 patients with a fractured IVCF out of 363 patients and 50% of patients without a fracture had imaging follow-up of less than four months. 37% of the patients died during the study. The combination of patients with a non-fractured IVCF who either died or were lost to follow-up (last imaging study less than five years post IVCF placement) during the study was large and are known as censored observations. The Kaplan-Meier survival estimates will be unreliable if the censored events are numerous, particularly when assessing a low frequency event, such as an IVCF fracture, which is not an inevitable event such as death. Kaplan-Meier survival estimates work well for inevitable events and high frequency events, but not as well for low frequency events, like IVCF fractures.

It is unclear, in the An paper, how the authors obtained the result of a point prevalence G2 IVCF fracture rate of 38% at five years. Prevalence is defined as the proportion of subjects in a population who have a particular disease or attribute at a specified point in time or over a specified period of time. Point prevalence refers to the prevalence measured at a particular point in time. It is the proportion of persons with a particular disease or attribute on a particular date. Period prevalence refers to prevalence measured over an interval of time. It is the proportion of persons with a particular disease or attribute at any time during the interval (84). In the An study, the period prevalence at five years would have been a better indicator of true fracture rate at five years. This could have included the numerator as 12, but the denominator could have been all subjects evaluated up to that point, including those that died and those that were evaluated at any time before five years, not just the 20 patients that were found to not have a fracture at five years. This number would have been much lower than 38%. It appears that An used a numerator that could have been applied to the five-year period

prevalence, but a denominator that could have been applied to the five-year point prevalence. This caused their five-year point prevalence fracture rate to be artificially high. It is no surprise that I know of no other study that shows a G2 IVCF fracture rate approaching 38%.

Hull also performed a retrospective study of Bard Recovery IVCFs in only 14 patients, and discovered a 21% fracture rate with mean follow-up of 899 days (74). The main limitation of this study was the power, as 14 subjects is very small and cannot provide statistical significance. This study was primarily descriptive and was an observational study which performed scanning electron microscopy of the four explanted fractured IVCFs.

Nicholson and colleagues also performed a small retrospective cross-sectional fluoroscopy study of only 28 Bard Recovery and 52 Bard G2 IVCFs (85). They showed fracture rates of 25% and 12% in Recovery and G2 IVCFs, respectively, using fluoroscopy imaging at a 37.8 months post implantation. Besides the weak study design and low power, particularly with the Recovery IVCF subjects, this study may have been limited by selection bias. As previously seen in the An and Tam studies, many of these patients already receive imaging of their IVCFs. Therefore, of the 80 patients who agreed to participate out of 189 patients (less than half), it is possible that some of the patients with known fractures were “encouraged” to participate more than those without known fractures. Also, this study seems to have been hampered by inaccurate reporting of the numbers of subjects, as the primary author published a correction two years later.

Frequently Cited Studies of Low IVCF Fracture Complications

Many studies have shown much lower fracture rates of Bard Recovery and Bard G2 IVCFs. To be clear, many of these studies are fraught with the same limitations as the studies that show high fracture rates in Bard optional IVCFs. A multicenter prospective study of the retrieval of 100 Bard G2 IVCFs showed no fractures in the 83 patients that were completely studied, although there was a 12% caudal migration rate of greater than 2 cm (86). Of note, like most caudal migrations, these were asymptomatic.

A retrospective evaluation of all IVCFs placed at a single institution over a 10 year period was performed. At a mean implantation to image time of 19.0 months, the 57 Bard G2 and G2X IVCFs had a fracture and/or embolization rate of 0%. Interestingly, all fractures involved the Cordis Trapease IVCF (87).

Cantwell and colleagues retrospectively compared Bard Recovery and G2 filters during the retrieval procedure (88). 67 Recovery and 60 G2 IVCFs were evaluated at a mean of 592 and 396 days, respectively. The fracture rates of the Recovery and G2 IVCFs were 9% and 0%, respectively.

Kalva and colleagues evaluated CT scans of 40 patients with a Bard Recovery IVCF at a mean of 80 days post implantation and found a 7.5% fracture rate (89).

Out of 140 G2 IVCF implantations, 26 patients had IVCFs removed at a mean period of 122 days post implantation in this study (90). Interestingly, the IVCF fracture and migration rates were both 0%.

An observational study of 107 Bard G2 IVCFs placed into 106 patients was performed. Follow-up CT scans were obtained at three and six months (91). Only one IVCF fracture was found for a fracture rate of 0.9%.

Zhu and colleagues found only 2 fractures in 139 patients with a Bard G2 IVCF who presented for retrieval using inferior vena cavograms in 131 and CT scans in 39 patients (92). 118 IVCFs were removed with a mean dwell time of 131.8 days.

A retrospective review of a prospectively collected database of fractured IVCFs was performed at a single institution (81). This study evaluated 548 patients presenting for IVCF removal, and found 63 fractured IVCFs (IVCF dwell time of 692 days), including foot process fractures. Excluding these and only considering arm or leg fractures, they found a fracture rate of 6%. Once again, this study is limited by its design and possible selection bias.

Another retrospective study of 64 IVCF retrievals, predominantly Bard Recovery and G2 IVCFs, showed a fracture rate of 12.5% with a mean IVCF dwell time of 172 days (93).

How Practicing Interventional Radiologists Decide on Which Device to Use

The average practicing Interventional Radiologist most likely makes an informed decision about which IVCF to place into his or her patients, based on multiple factors. These include personal experience (with current and predicate devices), review and critique of the available scientific IVCF literature, discussions with colleagues at venues such as scientific meetings and gatherings of all types, recommendations of peers, trust in the FDA to confidently evaluate and approve and clear IVCFs for medical use, general reputation of device manufacturers, the Instructions for Use by the manufacturers, black box warnings issued by the FDA, peer review and departmental quality assurance programs, and to a lesser degree, cost and institutional agreements and contracts with device manufacturers.

I have read multiple expert reports involved in this litigation, and many revolve around a common theme. Many of these reports that I have read have evaluated internal Bard documents. Personally, I can honestly state that I have never received confidential internal manufacturer communications, memoranda, in-house bench top and animal research, electronic mail, PowerPoint presentations, or product documents from Bard or any device manufacturer, other than surveys or questions about my opinions. Furthermore, I believe that most general practicing Interventional Radiologists are also not interested in learning about these internal communications, discussions, and documents, as most adverse event reports are unreliable and low on the hierarchy of scientific literature. These adverse event reports are very

confusing to interpret, since we often do not know the true numerators and denominators used to determine these purported complication rates. For example, the device manufacturer may know the number of devices sold, but not the true number placed into patients. Likewise, spontaneous and voluntary reporting, such as occurs with the FDA's Manufacturer and User Facility Device Experience Database (MAUDE) is not an accurate method of determining a complication rate for a device, as it introduces many biases and subjectivity.

Conclusion

IVCFs are life saving devices, which are often placed into patients without any other reasonable option to protect them from pulmonary embolism. Optional IVCFs are popular, since they can and should be removed percutaneously when no longer needed. Clinical follow-up programs that evaluate these patients in a timely fashion ensure that they do not miss their optimal window of opportunity for IVCF removal. The Bard optional IVCF *Instructions for Use*, the ACR/SIR/SPR guidelines, and many experts have recommended clinical follow up of optional IVCF patients for more than a decade. It is the responsibility of the interventionalists who place these optional IVCFs and/or the providers taking care of these patients to make a clinical assessment regarding retrieval once the risk of pulmonary embolism has passed. Indiscriminant imaging of an asymptomatic patient should not factor into these IVCF follow-up strategies and may be harmful. The available literature describing the complication rates of Bard retrievable IVCFs is understandably limited and the results should be interpreted with caution. I hold all of my opinions to a reasonable degree of medical certainty. I reserve the right to supplement this report if I receive additional pertinent information.

My hourly rate is $500.00.

Christopher S. Morris Date 4-13-17

Christopher S. Morris, MD

References

1. **Morris CS**, LaRosa J, and VanAman ME. Technically difficult percutaneous Kimray-Greenfield filter insertions. Presented at the 48th annual meeting, Ohio State Radiological Society; 1988 May 13; Toledo, OH.
2. Rogers FB, Shackford SR, Wilson J, Ricci MA, **Morris CS**. Prophylactic vena cava filter insertion in severely injured trauma patients: Indications and preliminary results. J Trauma 1993; 35:637-641.
3. Rogers FB, Strindberg G, Shackford SR, Osler TM, **Morris CS**, Ricci MA, Najarian KE, D'Agostino R, Pilcher DB. Five-year follow-up of prophylactic vena cava filters in high-risk trauma patients. Arch Surg 1998; 133:406-411.
4. **Morris CS**, Rogers FB, Najarian KE, Bhave AD, Shackford SR. Current trends in vena caval filtration with the introduction of a retrievable filter at a level I trauma center. J Trauma 2004; 57:32-36.
5. **Morris CS**, Cushman M. Perforation of the inferior vena cava by a Greenfield filter. Journal of Thrombosis and Haemostasis 2008; 6:1835-1836.
6. Winters J, **Morris CS**, Holmes C, et al. A multidisciplinary quality improvement program increases inferior vena cava filter retrieval rates. Vasc Med. 2017; 22(1):51-6.
7. 2016 Revised *ACR-SIR-SPR Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism.* https://www.acr.org/~/media/a569be8f18ae4cfaa2868b6e0984dbd8.pdf Accessed January 16, 2017.
8. Bard G2 Filter System. Femoral Vein Approach. Instructions for Use. http://www.bardpv.com/filterfacts/pdf/ifus/G2-Fem-BAW5250500-R2.pdf Accessed September 1, 2016.
9. U.S. Food and Drug Administration. Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use. August 9, 2010. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm221707.htm. Accessed on January 18, 2017.
10. U.S. Food and Drug Administration. Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication. May 6, 2014. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm396377.htm Accessed on January 18, 2017.
11. Kinney TB. Update on inferior vena cava filters. J Vasc Interv Radiol. 2003; 14(4):425-40.
12. Stein PD, Kayali F, Olson RE. Twenty-one-year trends in the use of inferior vena cava filters. Arch Intern Med 2004; 164:1541-1545.
13. Sing RF, Rogers FB, Novitsky YW, Heniford T. Optional vena cava filters for patients with high thromboembolic risk: questions to be answered. Surgical Innovation 2005; 12:195-202.
14. Duszak R Jr, Parker L, Levin DC. Placement and removal of inferior vena cava filters: National trends in the Medicare population. J Am Coll Radiol 2011; 8:483-9.

15. Spencer FA, Bates SM, Goldbert RJ. A population-based study of inferior vena cava filters in patients with acute venous thromboembolism. Arch Intern Med 2010; 170:1456-62.
16. Stein PD, Matta F, Jull RD. Increasing use of vena cava filters for prevention of pulmonary embolism. Am J Med 2011; 124:655-61.
17. Angel LF, Tapson V, Galgon RE. Systemic review of the use of retrievable inferior vena cava filters. J Vasc Interv Radiol 2011; 22:1522-30.
18. Helling TS, Kaswan S, Miller SL. Practice patterns in the use of retrievable inferior vena cava filters in a trauma population: A single-center experience. J Trauma 2009; 67:1293-6.
19. Sarosiek S, Crowther M, Sloan JM. Indications, complications, and management of inferior vena cava filters: The experience in 952 patients at an academic hospital with a level I trauma center. JAMA Intern Med 2013; 173:513-7.
20. Abtahian F, Hawkins BM, Ryan DP. Inferior vena cava filter usage, complications, and retrieval rate in cancer patients. Am J Med 2014; 127:1111-7.
21. Avgerinos ED, Bath J, Stevens J, et al. Technical and patient-related characteristics associated with challenging retrieval of inferior vena cava filters. Eur J Vasc Endovas Surg 2013; 46(3):353-9.
22. Kiguchi MM, Dillavou ED. IVC filters: challenges and future directions. Adv Vasc Med 2014; 2014:1-6.
23. Lee MJ, Valenti D, deGregorio MA, et al. The CIRSE retrievable IVC filter registry: retrieval success rates in practice. Cardiovasc Intervent Radiol 2015; 38:1502-7.
24. Peterson EA, Yenson PR, Liu D, Lee AYY. Predictors of attempted inferior vena cava filters retrieval in a tertiary care centre. Thromb Res 2014; 134:300-4.
25. U.S. Food and Drug Administration. Device Post Market Surveillance. http://www.fda.gov/MedicalDevices/Safety/CDRHPostmarketSurveillance/default.htm Accessed on January 20, 2017.
26. U.S. Food and Drug Administration. National Evaluation System for health Technology. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm Accessed on January 20, 2017.
27. Roberts PR. Follow up and optimization of cardiac pacing. Heart. 2005; 91(9):1229-34.
28. [Guideline] Guyatt GH, Akl EA, Crowther M, Gutterman DD, Schuünemann HJ, American College of Chest Physicians Antithrombotic Therapy and Prevention of Thrombosis Panel. Executive summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012 Feb. 141 (2 Suppl):7S-47S.
29. Kearon C, Akl EA, Ornelas J, Blaivas A, Jimenez D, Bounameaux H, Huisman M, King CS, Morris TA, Sood N, Stevens SM, Vintch JR, Wells P, Woller SC, Moores L. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. Chest. 2016;149(2):315-52.
30. Barritt DW, Jordan SC. Anticoagulant drugs in the treatment of pulmonary embolism. A controlled trial. Lancet 1960;1(7138):1309–1312.

31. Alpert JS, Smith R, Carlson J, Ockene IS, Dexter L, Dalen JE. Mortality in patients treated for pulmonary embolism. JAMA 1976;236(13):1477–1480.
32. Bauer G. The introduction of heparin therapy in cases of early thrombosis. Circulation 1959;19(1):108–109.
33. Raschke RA, Reilly BM, Guidry JR, Fontana JR, Srinivas S. The weight-based heparin dosing nomogram compared with a "standard care" nomogram. A randomized controlled trial. Ann Intern Med 1993;119(9):874–881.
34. Decousus H, Leizorovicz A, Parent F, et al. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. Prévention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group. N Engl J Med 1998;338:409-15.
35. PREPIC Study Group. Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: The PREPIC (Prévention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. Circulation 2005;112:416-22.
36. Mismetti P, Laporte S, Pellerin O, et al. Effect of a retrievable inferior vena cava filter plus anticoagulation vs anticoagulation alone on risk of recurrent pulmonary embolism: a randomized clinical trial. JAMA 2015; 313:1627-35.
37. Stein PD, Matta F, Keyes DC, Willyerd G. Impact of vena cava filters on in-hospital case fatality rate from pulmonary embolism. Am J Med 2012; 125:478-84.
38. Proctor MC, Greenfield LJ. Pulmonary embolism: diagnosis, incidence and implications. Cardiovasc Surg. 1997; 5:77-81.
39. Sakuma M, Nakamura M, Nakanishi N, et al. Inferior vena cava filter is a new additional therapeutic option to reduce mortality from acute pulmonary embolism. Circ J. 2004; 68:816-21.
40. Kazmers A, Jacobs LA, Perkins AJ. Pulmonary embolism in Veterans Affairs Medical Centers: is vena cava interruption underutilized? Am Surg. 1999; 65:1171-5.
41. Stein PD, Matta F, Sabra MJ. Case fatality rate with vena cava filters in hospitalized stable patients with cancer and pulmonary embolism. Am J Med. 2013; 126:819-24.
42. Stein PD, Matta F. Vena cava filters in unstable elderly patients with acute pulmonary embolism. Am J Med 2014; 127:222-5.
43. Muriel A, Jimenez D, Aujesky D, et al. Survival effects of inferior vena cava filter in patients with acute symptomatic venous thromboembolism and a significant bleeding risk. J Am Coll Cardiol 2014; 63:1675-83.
44. Burge AJ, Freeman KD, Klapper PJ, Haramati LB. Increased diagnosis of pulmonary embolism without a corresponding decline in mortality during the CT era. Clin Radiol 2008;63(4):381–386.
45. Becattini C, Agnelli G. Acute pulmonary embolism: risk stratification in the emergency department. Intern Emerg Med 2007;2(2):119–129.
46. Torbicki A, Perrier A, Konstantinides S, et al., Task Force for the Diagnosis and Management of Acute Pulmonary Embolism of the European Society of Cardiology. Guidelines on the diagnosis and management of acute pulmonary embolism: the Task Force for the Diagnosis and Management of Acute Pulmonary Embolism of the European Society of Cardiology (ESC) Eur Heart J 2008;29(18):2276–2315.

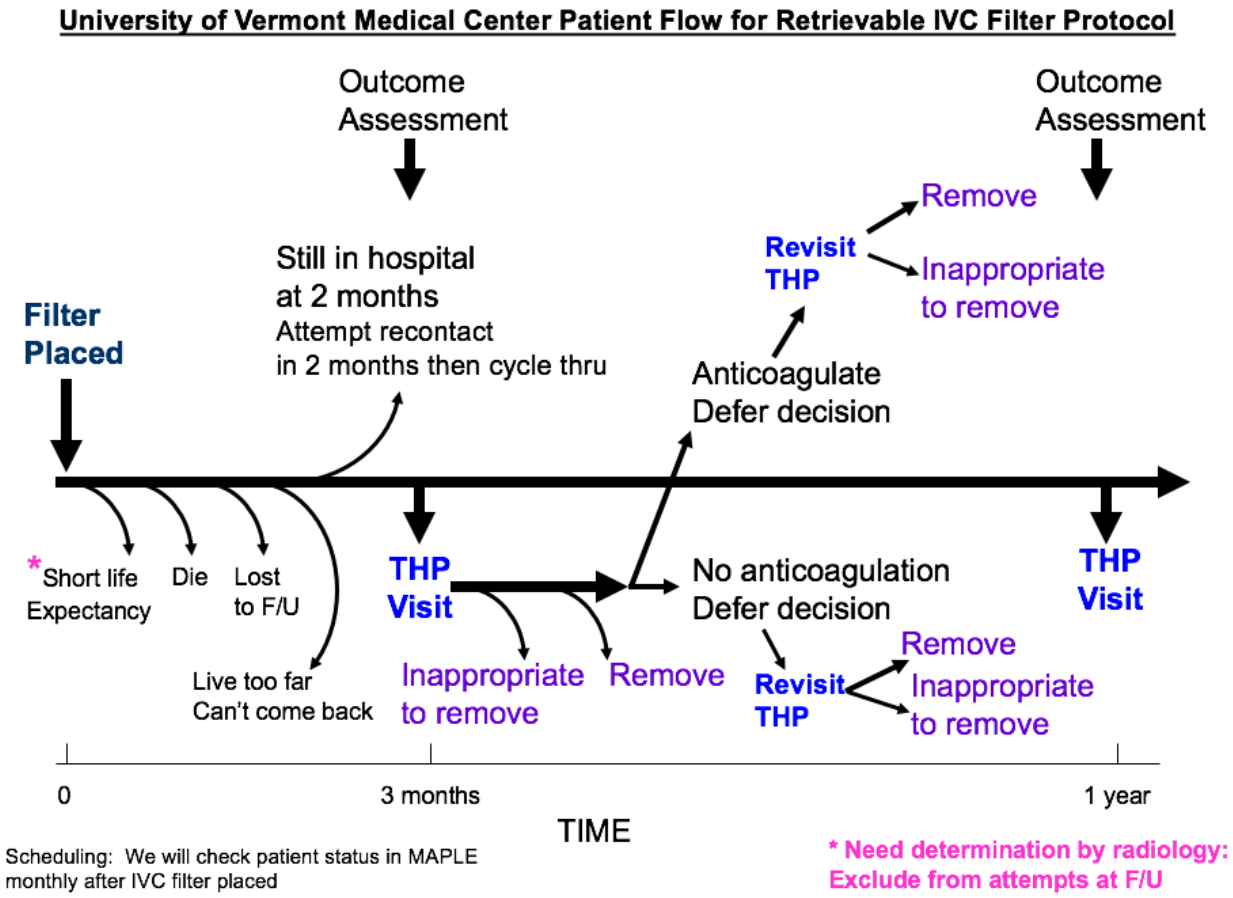
47. Sweet PH III, Armstrong T, Chen J, Masliah E, Witucki P. Fatal pulmonary embolism update: 10 years of autopsy experience at an academic medical center. JRSM Short Rep. 2013; 4(9):2042533313489824.
48. Anderson FA, Jr, Wheeler HB, Goldberg RJ, et al. A population based perspective of the hospital incidence and case-fatality rates of deep vein thrombosis and pulmonary embolism. Arch Intern Med 1991; 151: 933–8.
49. Weinberg I,Kaufman J, Jaff MR. Inferior vena cava filters. JACC Cardiovasc Interv. 2013;6(6):539-547.
50. Jaff MR, Kaufman J. A measured approach to vena cava filter use – respect rather than regret. JAMA Cardiol. 2017; 2(1):5-6.
51. Poletti PA, Becker CD, Prina L, et al. Long-term results of the Simon nitinol inferior vena cava filter. Eur Radiol. 1998; 8(2):289-94.
52. Bard Denali Vena Cava Filter. Femoral Vein Approach. Instructions for Use. http://www.bardpv.com/wp-content/uploads/2014/02/DenaliBAW5410500-US-FEM.pdf Accessed on January 20, 2017.
53. Ko SH, Reynolds BR, Nicholas DH, et al. Institutional protocol improves retrievable inferior vena cava filter recovery rate. Surgery 2009; 146:809-16.
54. Minocha J, Idakoji I, Riaz A, et al. Improving inferior vena cava filter retrieval rates: impact of a dedicated inferior vena cava filter clinic. J Vasc Interv Radiol 2010; 21:1847-51.
55. Irwin E, Byrnes M, Schultz S, et al. A systematic method for follow-up improves removal rates for retrievable inferior vena cava filters in a trauma patient population. J Trauma 2010; 69:866-9.
56. Lynch FC. A method for following patients with retrievable inferior vena cava filters: results and lessons learned from the first 1,100 patients. J Vasc Interv Radiol 2011; 22:1507-12.
57. Gasparis AP, Spentzouris G, Meisner RJ, et al. Improving retrieval rates of temporary inferior vena cava filters. J Vasc Surg 2011; 54:34S-8S.
58. Rogers FB, Shackford SR, Miller JA, et al. Improved recovery of prophylactic inferior vena cava filters in trauma patients: the results of a dedicated filter registry and critical pathway for filter removal. J Trauma 2012; 72:381-4.
59. Albrecht RM, Garwe T, Carter SM, Maurer AJ. Retrievable inferior vena cava filters in trauma patients: factor that influence removal rate and an argument for institutional protocols. Am J Surg 2012; 203:297-302.
60. Tan XL, Tam C, Mckellar R, Nandurkar H, Bazargan A. Out of sight, out of mind: an audit of inferior vena cava filter insertion and clinical follow up in an Australian institution and literature review. Intern Med J 2013; 43(4):365-72.
61. Sutphin PD, Reis SP, McKune A, et al. Improving inferior vena cava filter retrieval rates with the define, measure, analyze, improve, control methodology. J Vasc Interv Radiol 2015; 26:491-8.
62. Charlton-Ouw KM, Leake SS, Sola CN, et al. Technical and financial feasibility of an inferior vena cava filter retrieval program at a level one trauma center. Ann Vasc Surg 2015; 29:84-9.

63. Karp JK, Desai KR, Salem R, et al. A dedicated inferior vena cava filter service line: how to optimize your practice. Semin Intervent Radiol 2016; 33:105-8.
64. NCRP Report No. 160, Ionizing Radiation Exposure of the Population of the United States. http://ncrponline.org/publications/reports/ncrp-report-160/ Accessed on March 15, 2017.
65. Image Wisely. http://www.imagewisely.org Accessed on February 20, 2017.
66. Radiation Dose in X-ray and CT Exams. http://www.radiologyinfo.org/en/info.cfm?pg=safety-xray Accessed on February 20, 2017.
67. National Cancer Institute. https://www.cancer.gov/about-cancer/diagnosis-staging/ct-scans-fact-sheet Accessed on February 20, 2017.
68. Brenner DJ, Hall EJ. Computed tomography – an increasing source of radiation exposure. N Engl J Med 2007; 357:2277-84.
69. de Gonzalez AB, Mahesh M, Kim K-P; et al. Projected cancer risks from computed tomographic scans performed in the United States in 2007. Arch Intern Med. 2009; 169(22):2071-7.
70. "Should you worry about the radiation from CT scans?" https://www.washingtonpost.com/national/health-science/how-much-to-worry-about-the-radiation-from-ct-scans/2016/01/04/8dfb80cc-8a30-11e5-be39-0034bb576eee_story.html?utm_term=.67f42f94c11d Accessed on February 20, 2017.
71. Expert Report of Dr. Steven M. Hertz Regarding Medical Monitoring of Bard Retreivable IVC Filters 2017, paragraph #36 citing Bard Sales Data (BPV-17-01-00193291).
72. Expert Report of Mark J. Eisenberg, MD MPH FACC FAHA 2017, paragraph #89 citing Bard Sales Data (BPV-17-01-00193291).
73. Furtado CD, Aguirre DA, Sirlin CB, et al. Whole-body CT screening: spectrum of findings and recommendations in 1192 patients. Radiology 2005; 237(2):385-94.
74. Hull JE, Roberston SW. Bard recovery filter: evaluation and management of vena cava limb perforation, fracture, and migration. J Vasc Interv Radiol 2009; 20:52-60.
75. Rectenwald JE, Kaufman JA, Plant G. One Question… Endovascular Today July 2012, pp. 72-6.
76. Giroux M-F. Ask the experts: what is your practice's current IVC filter retrieval protocol, and in which cases do you deviate from it? Endovascular Today October 2015, pp. 53-58.
77. PRESERVE Trial (Predicting the Safety and Effectiveness of Inferior Vena Cava Filters) http://www.preservetrial.com/Study-Design accessed on February 26, 2017.
78. Laplante JS, Contractor FM, Kiproff PM, Khoury MB. Migration of the Simon nitinol vena cava filter to the chest. AJR Am J Roentgenol 1993; 160(2):385-6.
79. U.S. Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions accessed on March 6, 2017.
80. Oxford Centre for Evidence-based Medicine http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/)

(https://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/uspstf/index.html) accessed on March 6, 2017.

81. Vijay K, Hughes JA, Burdette AS, et al. Fractured Bard Recovery, G2, and G2 express inferior vena cava filters: incidence, clinical consequences, and outcomes of removal attempts. J Vasc Interv Radiol 2012; 23:188-94.
82. Tam MD, Spain J, Lieber M, et al. Fracture and distant migration of the Bard Recovery filter: a retrospective review of 363 implantations for potentially life-threatening complications. J Vasc Interv Radiol 2012; 23(2):199-205.
83. An T, Moon E, Bullen J, et al. Prevalence and clinical consequences of fracture and fragment migration of the Bard G2 filter: imaging and clinical follow-up in 684 implantations. J Vasc Interv Radiol 2014; 25:941-948
84. Centers for Disease Control and Prevention https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson3/section2.html accessed on March 6, 2017.
85. Nicholson W, Nicholson WJ, Tolerico P, et al. Prevalence of fracture and fragment embolization of Bard retrievable vena cava filters and clinical implications including cardiac perforation and tamponade. Arch Intern Med 2010; 170(20):1827-31.
86. Binkert CA, Drooz AT, Caridi JG, et al. Technical success and safety of retrieval of the G2 filter in a prospective, multicenter study. J Vasc Interv Radiol 2009; 20:1449-53.
87. Mitsunaga MM, Yoon H-C. Fracture rate and serious complications of vena cava filters. Open Journal of Radiology 2013; 3:85-90.
88. Cantwell CP, Pennypacker J, Singh H, Scorza LB, Waybill PN, Lynch FC. Comparison of recovery and G2 filter as retrievable inferior vena cava filters. J Vasc Interv Radiol 2009; 20:1193-9.
89. Kalva SP, Athanasoulis CA, Fan CM, et al. "Recovery" vena cava filter: experience in 96 patients. Cardiovasc Intervent Radiol 2006; 29:559-64.
90. Charles HW, Black M, Kovacs S, et al. G2 inferior vena cava filter: retrievability and safety. J Vasc Interv Radiol. 2009; 20:1046-51.
91. Damascelli B, Ticha V, Patelli G, et al. Use of a retrievable vena cava filter with low-intensity anticoagulation for prevention of pulmonary embolism in patients with cancer: an observational study in 106 cases. J Vasc Interv Radiol 2011; 22:1312-9.
92. Zhu X, Tam MD, Bartholomew J, et al. Retrievability and device-related complications of the G2 filter: a retrospective study of 139 filter retrievals. J Vasc Interv Radiol. 2011; 22:806-12.
93. Oh JC, Trerotola SO, Dagli M, et al. Removal of retrievable inferior vena cava filters with computed tomography findings indicating tenting or penetration of the inferior vena cava wall. J Vasc Interv Radiol 2011; 22:70-4.

Appendix 1



THP represents the Thrombosis and Hemostasis Program Clinic at the University of Vermont Medical Center

ATTACHMENT A

Chris Morris, MD ***Record of Testimony Given – 2007 to present***				
Case Name	***Court***	***Case No.***	***Date***	***Type***
Matthew Collins & Gillian Collins v. Dartmouth Hitchcock Medical Center, Hitchcock Clinic	New Hampshire	215-2012-cv-00207		Med-mal

ATTACHMENT B

Updated 4.10.17

Christopher S. Morris, M.D.
Christopher.Morris@uvmhealth.org

Business Address:

Department of Radiology
The University of Vermont Medical Center
111 Colchester Avenue
Burlington, VT 05401
(802)847-5684

Current Position:

Attending Radiologist University of Vermont Medical Center	1991 – Present

Academic Appointments:

Professor of Surgery University of Vermont College of Medicine	2016 – Present
Professor of Radiology University of Vermont College Medicine	2006 – Present
Associate Professor of Radiology University of Vermont College of Medicine	1999 – 2006
Honorary Clinical Assistant in Radiology Guy's and St. Thomas' Hospital Trust, United Kingdom	1998
Assistant Professor of Radiology University of Vermont College of Medicine	1991 – 1999
Clinical Assistant Harvard Medical School	1990 – 1991
Clinical Assistant Ohio State University School of Medicine	1986 – 1990

Education:

Vascular and Interventional Radiology Fellowship Massachusetts General Hospital, Boston, Massachusetts	1990 – 1991

M.S. Ohio State University Graduate School Columbus, Ohio	1990
Chief Resident, Diagnostic Radiology, Ohio State University Hospitals Columbus, Ohio	1988 – 1990
Resident, Diagnostic Radiology, Ohio State University Hospitals Columbus, Ohio	1986 – 1990
Intern in Medicine, Cleveland Metropolitan General Hospital Cleveland, Ohio	1985 – 1986
M.D. Case Western Reserve University School of Medicine Cleveland, Ohio	1985
B.A. Ohio Wesleyan University Delaware, Ohio	1981

Other Professional Positions and Employment:

Director, Division of Vascular and Interventional Radiology Fletcher Allen Health Care	2006 – 2010
Consultant Staff Gifford Memorial Hospital Randolph, VT	2007 – 2010
Courtesy Staff Radiologist Rutland Regional Medical Center Rutland, VT	1995 – 2004

Post Graduate Management/Leadership and Professional Training:

Horty Springer Leadership Training Course Las Vegas, Nevada	April 10 – 12, 2008

Certification and Licensure:

Nevada Medical License (#13411 – Inactive)	2009

New York Medical License (#246680)	2007 – Present
New Hampshire State Board of Medicine (#13633 – Inactive)	2007
The Medical Board of California (#G87223)	2004 – Present
Certificate of Registration as a Visiting Overseas Doctor (Registration #4460912) General Medical Council, United Kingdom	1998
American Board of Radiology - Certificate of Added Qualification In Vascular and Interventional Radiology	1995 – Present
State of Vermont Board of Medical Practice (#042-0008332)	1991 – Present
American Board of Radiology - Diagnostic Radiology	1990 – Present
Massachusetts Board of Registration in Medicine (#72682 – inactive)	1990
State Medical Board of Ohio (#53939 – inactive)	1985 – 1990

Professional Memberships & Activities (Active and Inactive):

American College of Radiology

Vermont Radiological Society

Radiological Society of North America

American Roentgen Ray Society

American Heart Association Council on Cardiovascular Radiology

Society of Interventional Radiology

International Society for Endovascular Surgery

New England Society of Cardiovascular and Interventional Radiology

Vermont Medical Society

Honors and Awards:

Division of the Year Interventional Radiology, Department of Radiology University of Vermont College of Medicine	2016
"Master Teacher," Teaching Academy University of Vermont College of Medicine	2016
Division of the Year Interventional Radiology, Department of Radiology University of Vermont College of Medicine	2013
Certificate of Merit Award Educational Exhibit. Abstract # LL-VIE4507 97th Scientific Assembly and Annual Meeting of the Radiological Society of North America.	2012
Becoming One Team Award of the University of Vermont Medical Center for the IVC Filter Multidisciplinary Management Team	2010
Fellow, American College of Radiology	2005
Fellow, Society of Interventional Radiology	2001
Visiting Professor, Kuwait University Health Sciences Center and Faculty of Medicine, Department of Radiology	Feb 21 – 27, 1999
Visiting Professor, Ohio State University Department of Radiology	Nov 20, 1992
Slocum Award for the Sciences, Ohio Wesleyan University Delaware, Ohio	1981
Phi Beta Kappa, Ohio Wesleyan University Delaware, Ohio	1980

Sabbaticals:

Vascular and Interventional Radiology Guy's Hospital, Department of Radiology London, United Kingdom. Sponsor: Professor A. Adam MBBS (Hons) FRCP FRCR	Jan 1998 – Mar 1998
Vascular and Interventional Radiology University of California, San Diego Medical Center San Diego, California.	Jan 2005 – Mar 2005

Sponsor: Ann Roberts, MD

University of Vermont and College of Medicine (UVM COM) Committees and Administrative Service:

Department of Radiology Chair Search Committee	2016 – Present
Curriculum Committee	2013 – 2016
Specialty Panel	Nov 11, 2012
New Curriculum Nephrology section	Nov, 2004
Fellowship Program Director, Vascular and Interventional Radiology	1999 – 2004
Residency Program Director, Diagnostic Radiology	1992 – 1996

The University of Vermont Medical Center (UVMMC) and the University of Vermont Medical Group (UVMMG) Department/Hospital Committees and Administrative Service:

Finance Committee – University of Vermont Medical Group	2016 – Present
Radiology Chair Search Committee	2016 – Present
Radiology Advancement Committee	2015 - Present
Cardiovascular Services, Interventional Radiology Representative	2014 – Present
Radiology Visiting Professor Committee	2010 - Present
Radiology Residency Core Curriculum Committee	2010 - 2016
Immediate Past President of the Medical Staff	2009 – 2010
President of the Medical Staff	2008 – 2009
Medical Staff Finance Committee – ex-officio member	2008 – 2009
Board of Trustees – ex-officio member	2008 – 2009
Patient Safety Committee – ex-officio member	2008 – 2009

Quality Assurance and Improvement Committee - ex-officio member	2008 – 2009
Bylaws Committee – ex-officio member	2008 – 2009
Vice President and President – Elect of the Medical Staff	2007 – 2008
Value Analysis Committee – Perioperative Services	2005 – 2010
Medical Staff Executive Committee	2004 – 2009
Credentials Committee	2003 – Present
Graduate Medical Education Committee	1999 – 2004
Fellowship Program Director, Vascular and Interventional Radiology	1999 – 2004
Compliance Committee	1998 – 2000
Residency Program Director, Diagnostic Radiology	1992 – 1996
Graduate Medical Education Committee	1992 – 1996

Regional Committees and Administrative Service:

Vermont ALS Center, Sponsored by the National ALS Association Interventional Radiology Representative	2006 – Present
Radiology Representative, Physician Policy Committee Vermont Medical Society	1999 – 2000
President, Vermont Radiological Society Vermont State Chapter of the American College of Radiology	1998 – 2000
Vice President / President Elect, Vermont Radiological Society Vermont State Chapter of the American College of Radiology	1996 – 1998
Secretary/Treasurer, Vermont Radiological Society Vermont State Chapter of the American College of Radiology	1994 – 1996

National Committees and Administrative Service:

Society of Interventional Radiology Annual Scientific Meetings SIR2012; San Francisco, CA Faculty - CVC Insertion - Clinical Associates Hands On Workshop	Mar 24, 2012

Research and Reports in Focused Ultrasound Editorial Board Member	2012 – Present
The Scientific World Journal Editorial Board Member	2011– Present
Society of Interventional Radiology Subcommittee of Complication Review Standards of Practice Committee	2013 – Present
Member, Data Monitoring and Safety Committee RETRIEVE I and RETRIEVE II Studies Crux Biomedical, Inc.	2008 – 2011
Society of Interventional Radiology 29th, 30th, 31st Annual Scientific Meetings Faculty and Workshop Coordinator. Inferior Vena Cava Filtration Hands On Workshops. Phoenix, AZ, New Orleans, LA, and Toronto, Canada	2004 – 2006
Society of Interventional Radiology 27th and 28th Annual Scientific Meetings Faculty. Inferior Vena Cava Filtration Hands On Workshop Baltimore, MD and Salt Lake City, UT	2002 – 2003
American Association of Academic Chief Residents in Radiology Steering Committee Member and Film Panel Moderator	1988 – 1989

Peer-Reviewed Publications:

O Khalilzadeh, M.O. Baerlocher, D Katsarelis, P Shyn, A Devane, **C Morris**, A Cohen, B Connolly, M Midia, R Thornton[1], K Gross, D Caplin, G Aeron, S Misra, N Patel, T Walker, G Martinez-Salazar, J Silberzweig, B Nikolic. Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee. Submitted to J Vasc Interv Radiol

Vincent JK, Stark C, Bhave AD, Shields JT, **Morris CS**: Hepatic venous pressure gradient as a predictor of advanced hepatic fibrosis: A retrospective review. Abdominal Radiology. In Press.

Ford C, Lange B, **Morris CS**: Transcatheter Embolization of Abdominal Aortic Endograft Endoleaks Using Onyx and Coils: Experience at a Regional Tertiary Care Referral Center. Journal of Vascular Diagnostics and Interventions 5:15-9; 2017.

Winters J, **Morris CS**, Holmes C, et al.: A multidisciplinary quality improvement program increases inferior vena cava filter retrieval rates. Vasc Med. 22(1):51-6; 2017.

Love R, Johnson M, Bhave AD, Shields JT, Scriver GM, **Morris CS**: Rotational CT during tunneled peritoneal dialysis catheter placement: predictor of catheter function and durability. Works in Progress.

Johnson J, Kiankhooy A, Bertges D, **Morris CS**: Image guided treatment of adventitial cystic disease of the femoral vein. Cardiovascular and Interventional Radiology 32:812-6; 2009.

Morris CS: Current status of renal arterial endovascular interventions. Invited Review. Current Hypertension Reviews 5:321-332; 2009.

Johnson J, Saemi A, **Morris CS**: Brief report: Transcatheter vasodilatation following thrombolytics for the treatment of frostbite. Cardiovascular and Interventional Radiology 32:1280-3; 2009.

Morris CS, Cushman M: Perforation of the inferior vena cava by a Greenfield filter. Journal of Thrombosis and Haemostasis 6:1835-1836; 2008.

Morris CS: Update on uterine artery embolization for symptomatic fibroid disease (uterine artery embolization). Abdominal Imaging. 33:104-11; 2008. Published online February 7, 2007.

Morris CS, Rogers FB, Najarian KE, Bhave AD, Shackford SR: Current trends in vena caval filtration with the introduction of a retrievable filter at a level I trauma center. J Trauma 57:32-36; 2004.

Schultze D, **Morris CS**, Bhave AD, Worgan BA, Najarian KE: Radiofrequency Ablation of Renal Transitional Cell Carcinoma with Protective Cold Saline Infusion. J Vasc Interv Radiol 14:489-492; 2003.

Morris CS: Role of vascular and interventional radiology in the diagnosis and management of acute trauma patients. J Intensive Care Med 17:112-126; 2002.

Morris CS: Vascular and solid organ trauma - Interventional Radiology. emedicine.com; accessible at http://www.emedicine.com/radio/topic881.htm; 2001.

Morris CS, Bonnevie G, Najarian KE: Nonsurgical treatment of acute iatrogenic renal artery injuries occurring after renal artery angioplasty and stenting. AJR. Am J Roentgenol 177:1-5; 2001.

Morris CS, Nelson EN, Najarian KE, D'Agostino R: Case report: Treatment of acute aortorenal bypass graft thrombosis using primary stenting and adjunctive thrombolysis. J Vasc Interv Radiol 9:961-963, 1998.

Morris CS, Najarian KE: Transjugular intrahepatic portosystemic shunt for bleeding stomal varices associated with chronic portal vein occlusion: long-term angiographic, hemodynamic, and clinical follow-up. Am J Gastroenterol 95(10):2966-8, 2000.

Rogers FB, Strindberg G, Shackford SR, Osler TM, **Morris CS**, Ricci MA, Najarian KE, D'Agostino R, Pilcher DB: Five-year follow-up of prophylactic vena cava filters in high-risk trauma patients. Arch Surg 133:406-411, 1998.

Chapdelaine JP, Najarian KE, D'Agostino R, **Morris CS**: Stent placement in a carotid artery bypass graft in a patient with Takayasu arteritis. J Vasc Interv Radiol 9:846-848, 1998.

Najarian KE, **Morris CS**: Transcatheter arterial embolization in the chest (AVMs, bronchial artery embolization). Journal of Thoracic Imaging 13:93-104, 1998.

Ahmad A, Najarian KE, **Morris CS**: Case Report. Percutaneous treatment of a collapsed stent-graft. J Vasc Interv Radiol 8:637-639, 1997.

Rogers FB, Shackford SR, Wilson J, Ricci MA, **Morris CS**: Prophylactic vena cava filter insertion in severely injured trauma patients: Indications and preliminary results. J Trauma 35:637-641, 1993.

Morris CS: Master's Thesis: Microcomputer assisted tutorial in neuroradiology. The Ohio State University Press. Sept 1990.

Morris CS: Roentgenologic clinical pathologic case: Paget's disease with headache and disorientation. Investigative Radiology 25:1279-1284, Nov 1990.

Morris CS, Chirico PA: Case form A^3CR^2: Comatose young woman with respiratory distress and abdominal mass. Investigative Radiology 25:1159-1161, Oct 1990.

Morris CS, Lough LR, Weinberger E: Case from A^3CR^2: Infant with lethargy, failure to thrive, and abnormal blood smear. Investigative Radiology 25:1054-1057, Sept 1990.

Morris CS, Lloyd T: Case report: Traumatic scapulothoracic dissociation in a child. Skeletal Radiology 19:607-608, Sept 1990.

Morris CS, Beltran JL: Giant synovial cyst associated with a pseudarthrosis of a rib: MR appearance. AJR. Am J Roentgenol 155:337-338, Aug 1990.

Chandnani VP, Beltran J, **Morris CS**, et al.: Acute experimental osteomyelitis and abscesses: detection with MR imaging versus CT. Radiology 174:233-236, 1990.

McGhee RB, Bennett WF, **Morris CS**, Witanowski LS: Cost-effective development of a computer-assisted instruction system. AJR. Am J Roentgenol 153:877-879, Oct 1989.

Invited Author for Chapter:

Morris CS and Rimmer JM: Diagnostic and therapeutic renal angiography. In: Schrier RW (ed.) *Diseases of the Kidney and Urinary Tract* 8th ed. Philadelphia: Lippincott, Williams, and Wilkins. 2006.

Morris CS and Rimmer JM: Diagnostic and therapeutic renal angiography. In: Schrier RW (ed.) *Diseases of the Kidney and Urinary Tract* 7th ed. Philadelphia: Lippincott, Williams, and Wilkins. 2001.

Morris CS and Rimmer JM: Diagnostic and therapeutic renal angiography. In: Schrier RW and Gottschalk CW (eds.) *Diseases of the Kidney* 6th ed. Boston: Little, Brown and Co. 1997

National/International
Abstract Poster/Electronic Exhibit
Presentations:

McGhee RB, Bennett WF, **Morris CS**, Witanowski LS. Cost-effective development of a computer-assisted instruction system. Presented as a scientific exhibit at the 74th Scientific Assembly and Annual Meeting of the RSNA; 1988 Nov; Chicago, IL.

McGhee RB, Bennett WF, **Morris CS**, Witanowski LS. Cost-effective development of a computer-assisted instruction system. Presented as a scientific exhibit at the 37th Annual Meeting of the Association of University Radiologists; 1989 May; Seattle, WA.

Morris CS, LaRosa J, and VanAman ME. Technically difficult percutaneous Kimray-Greenfield filter insertions. Presented at the 48th annual meeting, Ohio State Radiological Society; 1988 May 13; Toledo, OH.

Regional Abstract
Oral Presentations:

Conor O'Neill, MD; Tess Aulet, MD; Sergey Kulikov, MD; Douglas Sutton, RN; **Christopher Morris, MD**; Joseph Shields, MD; Carlos Marroquin, MD, FACS; Anant Bhave, MD: Interventional Strategies for Management of Hepatocellular Carcinoma at UVMMC; Presented at the Vermont Chapter of the American College of Surgeons Annual Meeting, 26 May, 2016; South Burlington, VT.

Fernandez N, Stanley AC, Healey C, Osler T, Pilcher DB, Ricci MA, Steinthorsson G, **Morris CS**, Shackford SR: Clinical outcomes of percutaneous revascularization as an isolated procedure in treating patients with limb threatening ischemia. Presented at the New England Society for Vascular Surgery 30th Anniversary Meeting; 2003 Sept 19-21; Albany, NY.

Rogers FB, Shackford SR, Osler TM, **Morris CS**, Najarian KE, D'Agostino RM, Strindberg G, Ricci, MR: Five year follow-up of prophylactic vena cava filters in high risk trauma patients: complications and results. Presented at the New England Surgical Society Annual Meeting; 1997 Sept 20; Bolton Landing, NY.

Morris CS. Radiology of pulmonary embolism. Presented at the Edward F. Morris, M.D. Symposium, Barberton Citizens Hospital; 1988 June 18; Barberton, OH.

National/International
Abstract Oral or Poster Presentations:

O Khalilzadeh, M.O. Baerlocher, D Katsarelis, P Shyn, A Devane, **C Morris**, A Cohen, B Connolly, M Midia, R Thornton[1], K Gross, D Caplin, G Aeron, S Misra, N Patel, T Walker, G Martinez-Salazar, J Silberzweig, B Nikolic. Proposal of a New Adverse Event Classification by the SIR Standards of Practice Committee. Submitted as an oral presentation to the 42nd Annual Meeting of the Society of Interventional Radiology; 2017 Mar 4 – 9; Washington D.C.

Love R, Johnson M, Bhave AD, Shields JT, Scriver GM, **Morris CS**: Rotational CT during tunneled peritoneal dialysis catheter placement: predictor of catheter function and durability. Works in Progress.

Ali NS, Allison JB, **Morris CS**, D'Agostino RM: Clinical vignette: Spontaneous duodenal hematoma in an anticoagulated patient. Abstract presentation at the American Medical Association Research Symposium; 2016 Nov 11; Orlando, FL

Qian J, Shields JT, Allison JB, Bhave AD, **Morris CS**: Fluoroscopic Time Requirement as Predication of Successful IVC Filter Retrieval. Oral Presentation at the 102nd Scientific Assembly and Annual Meeting of the Radiological Society of North America, McCormick Place; 2016 Nov 27 – Dec 2; Chicago, IL.

Vincent JK, Stark C, **Morris CS**: Hepatic venous pressure gradient as a predictor of advanced hepatic fibrosis: A retrospective review. Scientific Poster Presentation at the American Roentgen Ray Society Annual Meeting; 2015 Apr 19 – 24; Toronto, Canada.

Winters J, **Morris CS**, Holmes C, et al.: A multidisciplinary quality improvement program increases inferior vena cava filter retrieval rates. Presented as a Scientific Poster (#162) at the Thrombosis and Hemostasis Summit of North America (THSNA); 2014 Apr 11; Chicago, IL.

Baumann CJ, **Morris CS**, Bhave AD, Najarian, KE: Compression of the anomalous median artery of the wrist. Abstract #358. Presented as a Scientific Poster at the 39th Annual Meeting of the Society of Interventional Radiology; 2014 Mar 22 – 27; San Diego, CA.

Lange B, **Morris CS**, Najarian KE: Transcatheter Embolization of Abdominal Aortic Endograft Endoleaks Using Onyx and Coils: Experience at a Regional Tertiary Care Referral Center. Oral Scientific Presentation of the 98th Scientific Assembly and Annual Meeting of the Radiological Society of North America, McCormick Place; 2012 Nov 24 – 30; Chicago, IL.

Lemos JA, Pace WA, Bhave AD, Scriver G, Shields JT, Najarian KE, **Morris CS**: "Embolization and Obliteration of the Injured Biliary Ductal System Using Microcoils and N-Butyl Cyanoacrylate." Educational exhibit presentation at the 97th Scientific Assembly and Annual Meeting of the Radiological Society of North America. McCormick Place; 2011 Nov 27-Dec 2; Chicago, IL.

Lemos JA, Hampson CO, **Morris CS**, Bhave AD, Shields JT, Najarian KE: "Percutaneous Treatment of the Injured Biliary Tree." Educational exhibit presentation at the 95th Scientific Assembly and Annual Meeting of Radiology Society of North America (RSNA); 2009 Nov. 29 – Dec 04; Chicago, IL.

Lemos JA, Cushman M, Bhave AD, Najarian KE, Shields JT, **Morris CS**: "Increased Inferior Vena Cava Filter Retrieval Rate With Improved Clinical Follow-Up." Scientific exhibit presentation at the 2009 Meeting of Cardiovascular and Interventional Radiological Society of Europe; 2009 Sept 19-23; Lisbon, Portugal.

Panko JE, **Morris CS**: Increased retrieval rates and dwell times for optional inferior vena cava filters at a level I trauma center: do improved patient follow-up and new inferior vena cava filter designs make a difference? Presented as a Scientific Poster at the Radiological Society of North America (RSNA) 92nd Scientific Assembly and Annual Meeting; 2006 Nov 26 – Dec 1; Chicago, IL.

Morris CS, Rogers FB, Najarian KE, Bhave AD, Shackford SR: Current trends in vena caval filtration with the introduction of a retrievable filter at a level I trauma center. Presented as a scientific poster at the 63rd Annual Meeting of the American Association for the Surgery of Trauma; 2003 Sept 9-11; Minneapolis, MN.

Ricci MA, **Morris CS**, Forgione MD, Callas PW, and the Wallgraft Occlusive Trial Investigators: Primary endovascular grafting of iliac occlusive disease is superior to stent alone - Initial results from a randomized, multicenter trial. Presented at the American Association for Vascular Surgery; 2001 June 12; Baltimore, MD.

Gemery JM, **Morris CS**, Najarian KE: Percutaneous transcatheter treatment of the failing lower extremity bypass graft. JVIR (suppl 2) 8:213, 1997. Presented at the Society of Interventional Radiology 22nd Annual Scientific Meeting; 1997 Mar 8-13; Washington D.C.

Rogers FB, Shackford SR, Wilson J, Kaups KL, Ricci MA, Wald S, **Morris CS**: Prophylactic vena cava filter insertion in severely injured trauma patients: Indications and preliminary results. E.A.S.T. 32:953, 1992. Hamilton, Bermuda.

McGhee RB, Bennett WF, **Morris CS**, Witanowski LS: Cost-effective development of a computer-assisted instruction system. 37th Annual Meeting of the Association of University Radiologists; 1989 May; Seattle, WA.

McGhee RB, Bennett WF, **Morris CS**, Witanowski LS: Cost-effective development of a computer-assisted instruction system. Scientific exhibit at the 74th Scientific Assembly and Annual Meeting of the RSNA; 1988 Nov; Chicago, IL.

Regional Invited
Speaking Engagements:

UVM College of Medicine Surgery Readiness Course. 2016 Mar 7; Burlington, VT.

UVM College of Medicine Surgery Readiness Course. 2015 Mar 2; Burlington, VT.

UVM College of Medicine Surgery Readiness Course. 2014 Mar 4; Burlington, VT.

NMGI Mock Tumor Board. UVM College of Medicine; 2013 Mar 14; Burlington, VT.

Interventional Radiology of GI Bleeding. GI Core Curriculum Conference. Department of Medicine. UVM College of Medicine; 2013 Feb 26; Burlington, VT.

Interventional Radiology in the Abdomen. Surgery Resident Readiness Course. UVM College of Medicine; 2012 Mar 5; Burlington, VT.

Tumor Ablation. Pathology Research Forum. Department of Pathology. UVM College of Medicine; 2012 Feb 3; Burlington, VT.

Interventional Radiology Applications in the ICU. The 9th Annual Northern New England Critical Care Conference; 2011 Oct 21; Stowe, VT.

Interventional Radiology 2011. Grand Rounds. Department of Surgery. UVM College of Medicine; 2011 Apr 14; Burlington, VT.

Interventional Radiology for the Future Surgery Intern. Surgery Majors of UVM College of Medicine; 2011 Mar 16; Burlington, VT.

Interventional Radiology in Trauma: What is it, who are we, and what can it / we do for the trauma patient and trauma surgeon? The New England Regional Trauma Conference; 2008 Oct 2; Shrewsbury, MA.

Vascular Access Emergencies. Fletcher Allen Health Care Division of Nephrology Pathophysiology Conference; 2008 Mar 21; Burlington, VT.

Abdominal Aortic Aneurysms. Candidacy (anatomic issues), Devices, Domplications, and Follow-up of Endografts. Grand Rounds. Rutland Regional Medical Center; 2007 Jan 18; Rutland, VT.

Aortic Stent-Grafts and CTA. The 20th Annual Imaging Seminar. The University of Vermont College of Medicine; 2006 Oct 13; Stowe, VT.

Update on Inferior Vena Cava Filters. Vermont Vascular Medicine Conference; 2006 Oct 6; Burlington, VT.

Management of Abdominal Aortic Aneurysms. Grand Rounds. Porter Hospital; 2006 Sept 29; Middlebury, VT.

Aortic stent-grafts. Grand Rounds. Department of Radiology. University of Vermont College of Medicine; 2005 Dec 16; Burlington, VT.

Endoleaks associated with abdominal aortic stent-grafts: Past, present, and future. Grand Rounds. Department of Surgery. University of Vermont College of Medicine; 2005 Mar 31; Burlington, VT.

New topics in Interventional Radiology. The University of Vermont CME Regional Program. Copley Hospital Medical Staff; 2002 Feb 13; Morrisville, VT.

Update on uterine artery embolization for symptomatic uterine fibroid disease. Grand Rounds. Department of Obstetrics and Gynecology. University of Vermont College of Medicine; 2001 Nov 6; Burlington, VT.

What's new in vascular and interventional radiology Grand Rounds. Department of Family Practice, University of Vermont College of Medicine; 2001 Mar 12; Burlington, VT.

Transjugular intrahepatic portosystemic shunt. Panel discussion. Stowe Conference on Digestive Diseases. University of Vermont College of Medicine; 2001 Mar 3; Stowe, VT.

Uterine artery embolization for symptomatic fibroid disease. The University of Vermont CME Regional Program. Springfield Hospital Medical Staff; 2001 Feb 15; Springfield, VT.

Angiography and interventional radiology in trauma. New England Roentgen Ray Society; 2000 Oct 13 Boston, MA.

Bronchial artery embolization and uterine artery embolization. 42nd Annual New England Conference of Radiologic Technologists; 2000 Sept 16; Burlington, VT.

MR Angiography. Vascular physics and technology review course. Department of Surgery, University of Vermont College of Medicine; 1999 Oct 25; Burlington, VT.

Radiologic management of the failing and thrombosed dialysis graft. Grand Rounds. Department of Surgery. University of Vermont College of Medicine; 1999 May 27; Burlington, VT.

Peripheral magnetic resonance angiography. Grand Rounds. Department of Radiology. University of Vermont College of Medicine; 1999 Jan 14; Burlington, VT.

Uterine artery embolization for the treatment of symptomatic uterine fibroids. Grand Rounds. Department of Obstetrics and Gynecology. University of Vermont College of Medicine; 1998 May 19; Burlington, VT.

Management of peripheral vascular disease. Vermont Academy of Family Physicians Annual Meeting; 1998 May 7; Killington, VT.

Bronchial artery transcatheter embolization in hemoptysis. Grand Rounds. Department of Radiology. University of Vermont College of Medicine; 1997 Apr 11; Burlington, VT.

Peripheral vascular disease. 38th Annual New England Conference of Radiologic Technologists; 1996 Sept 20; Burlington, VT.

Multidisciplinary approach to the management of portal hypertension. Grand Rounds. Department of Surgery. University of Vermont College of Medicine; 1996 Sept 12; Burlington, VT.

Current status of transjugular intrahepatic portosystemic shunts (TIPS). Fourth Annual Current Concepts and Controversies in Surgery. Department of Surgery, University of Vermont College of Medicine; 1995 Feb 9; Stowe, VT.

Angiography. Vascular physics and technology review course. Department of Surgery, University of Vermont College of Medicine; 1994 Sept 6; Burlington, VT.

Transjugular intrahepatic portosystemic shunts (TIPS) and other radiologic interventions. Clinical Problems in Gastroenterology X, UVM College of Medicine, Gastroenterology Unit; 1993 Feb 2; Stowe, VT.

Transjugular intrahepatic portosystemic shunt (TIPS). Grand Rounds, Department of Surgery, University of Vermont College of Medicine; 1993 Jan 28; Burlington, VT.

Transjugular intrahepatic portosystemic shunt (TIPS). Experience at MCHV. Grand Rounds, Department of Radiology, University of Vermont College of Medicine; 1992 Nov 10; Burlington, VT.

Transjugular intrahepatic portosystemic shunt. Presented at the Division of Gastroenterology, Department of Internal Medicine weekly conference, University of Vermont College of Medicine; 1992 June 25; Burlington, VT.

National/International Invited Speaking Engagements:

Central Venous Catheter Insertion. CVC Insertion. Clinical Associates Hands On Workshop. Society of Interventional Radiology Annual Scientific Meetings, SIR2012; 2012 Mar 24; San Francisco, CA.

The Cold Foot. The New England Roentgen Ray Society Program; 2008 Apr 4; Boston, MA.

Interventional Radiology for the Family Physician. New York State Academy of Family Physicians Winter Weekend and 59th Scientific Assembly; 2007 Jan 27; Lake Placid, NY.

Uterine Arterial Embolization. 26th Annual Comprehensive Review of Vascular and Interventional Radiology. Department of Radiology, University of California, San Diego; 2006 Oct 28; San Diego, CA.

Stent Grafts. 26th Annual Comprehensive Review of Vascular and Interventional Radiology. Department of Radiology, University of California, San Diego; 2006 Oct 28; San Diego, CA.

Update on renal arterial interventions. 26th Annual Comprehensive Review of Vascular and Interventional Radiology. Department of Radiology, University of California, San Diego; 2006 Oct 27; San Diego, CA.

Interventional Radiology of Biliary Disease. 1st Gulf Radiological Society Conference and 4th Kuwait International Conference of Radiology and Nuclear Medicine; 2006 Apr 20; Kuwait City, Kuwait.

Update on Inferior Vena Cava Filters. 1st Gulf Radiological Society Conference and 4th Kuwait International Conference of Radiology and Nuclear Medicine; 2006 Apr 19; Kuwait City, Kuwait.

Current status of inferior vena cava filtration. Inferior Vena Cava Filtration Hands On Workshop. Society of Interventional Radiology 31th Annual Scientific Meeting; 2006 Mar 31 and April 2; Toronto, CA.

Uterine artery embolization. University of California at San Diego Radiology Review Course: 25th Annual Comprehensive Review of Vascular and Interventional Radiology; 2005 Oct 22; San Diego, CA.

Stent-grafts in aortic diseases. University of California at San Diego Radiology Review Course: 25th Annual Comprehensive Review of Vascular and Interventional Radiology; 2005 Oct 22; San Diego, CA.

Current status of inferior vena cava filtration. Inferior Vena Cava Filtration Hands On Workshop. Society of Interventional Radiology 30th Annual Scientific Meeting; 2005 Apr 2& 4; New Orleans, LA.

Case Presentations. Radiology Residency Noon Conference. University of California, San Diego, VA Hospital; 2005 Mar 22; La Jolla, CA.

Interventional Radiology of biliary disease. Grand Rounds. Department of Radiology. UCSD Medical Center, Hillcrest Hospital; 2005 Mar 22; San Diego, CA.

Role of interventional radiology in trauma. Radiology Residency Noon Conference. University of California, San Diego, VA Hospital; 2005 Feb 15; La Jolla, CA.

Endoleaks associated with abdominal aortic stent grafts: Past, present, and future. San Diego Angio Club. Thornton Hospital; 2005 Jan 12; San Diego, CA.

Current status of inferior vena cava filtration. Culinary Institute; 2004 May 10; Poughkeepsie, NY.

Current status of inferior vena cava filtration. Syracuse Angio Club; 2004 Apr 14; Syracuse, NY.

Current status of inferior vena cava filtration. Inferior Vena Cava Filtration Hands On Workshop. Society of Interventional Radiology 29th Annual Scientific Meeting; 2004 Mar 26&29; Phoenix, AZ.

Current status of inferior vena cava filtration. Mercy Hospital; 2004 Feb 3; Portland, Maine.

Bronchial artery embolization. The Second International Conference of Radiology and Nuclear Medicine. Kuwait Radiology Society; 1999 Feb 22; Kuwait City, Kuwait.

Uterine artery embolization for symptomatic uterine fibroid disease. The Second International Conference of Radiology and Nuclear Medicine. Kuwait Radiology Society; 1999 Feb 22; Kuwait City, Kuwait.

Carbon dioxide angiography. The Second International Conference of Radiology and Nuclear Medicine. Kuwait Radiology Society; 1999 Feb 21; Kuwait City, Kuwait.

Current status of transjugular intrahepatic portosystemic shunt (TIPS). Department of Radiology, Ohio State University College of Medicine; 1992 Nov 20; Columbus, OH.

Invited Reviewer:

Reviewer, Journal of Vascular and Interventional Radiology	2011 – 2014
Senior Reviewer, Journal of Trauma	2000 – 2010
Reviewer, American Journal of Roentgenology	1997 – 2004

Active and Inactive Clinical Research:

Sub-Investigator: National Multicenter Trial. National Cancer Institute (NCI) – Molecular Analysis for Therapy Choice (NCI-MATCH) Trial EAY131	2017 – Present
Sub-Investigator: CHRMS 16-719 National Multicenter Trial - Conatus 12. Multicenter, randomized, double-blind, Placebo-controlled trial of Emricasan, an oral caspase inhibitor, in (IDN-6556) in subjects with non-steatohepatitis (NASH) fibrosis.	2017 - Present
Sub-Investigator: CHRMS 17-0192 National Multicenter Trial - Conatus 12. Multicenter randomized, double-blind, Placebo-controlled trial of Emricasan, an oral caspase inhibitor, in (IDN-6556) in subjects with non-steatohepatitis (NASH) fibrosis and severe portal hypertension.	2017 - Present
Principal Investigator: Adjunctive cone-beam CT as a predictor of tunneled peritoneal dialysis catheter function. University of Vermont Medical Center Single Center Trial	2015 – Present
Co-principal Investigator: National Multicenter Trial. Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia (BEST-CLI)	2014 – Present
Co-investigator: National Multicenter Trial. ALLOCURE Phase 2 Clinical Trial in Acute Kidney Injury. Novel Cell Therapy AC607	2012 – 2014
Co-investigator: National Multicenter Trial. ORION trial. Boston Scientific Corporation.	2008 – 2010
Principal Investigator: Prospective evaluation of inferior vena cava filters. University of Vermont Medical Center Single Center Trial. Departments of Radiology, Medicine, and Surgery	2007 – 2012
Co-investigator: National Multicenter Post-market Trial. CHOICE trial. Abbott Corporation.	Jan 2007 – 2012

Principal Investigator: National Multicenter Trial. Feb 2006 – 2007
Wallgraft Occlusive Trial. Boston Scientific Corporation.

Principal Investigator: National Multicenter Trial. Dec 2005 – 2007
EVEREST Recovery Filter Study.
BARD Peripheral Vascular, Inc. (no patients enrolled)

Co-investigator: National Multicenter Post-market Trial. Oct 2004 – Oct 2006
CAPTURE: Carotid ACCULINK/ACCUNET Post Approval
Trial to Uncover Rare Events. Guidant Corporation.

Principal Investigator: National Multicenter Trial. Dec 2001 – Dec 2002
A multicenter, phase 3 study to determine the safety
and efficacy of MS-325-enhanced MRA in patients
with suspected peripheral vascular disease.
Epix Medical, Inc. and Mallinkrodt.

Principal Investigator: Observational study of renal artery angioplasty May 2001 – May 2002
and stenting using carbon dioxide and iodinated contrast media.
Single Center Study. Department of Radiology.
University of Vermont College of Medicine.

Co-investigator: National Multicenter Trial. Feb 2001 – 2004
RESTORE: Renal stent for the treatment of renovascular hypertension.
IntraTherapeutics, Inc.

Co-investigator: National Multicenter Trial. Jan 2001 –Mar 2001
A randomized double blind study comparing the safety
and efficacy of enoxaparin 30 mg q 12 hours, enoxaparin 40 mg qd
with placebo and Na heparin 5000 u q12 hours as prophylaxis
against DVT and PE after trauma.
Aventis Pharmaceuticals, Inc.

Principal Investigator: National Multicenter Trial. Aug 2000 – Dec 2000
A phase 2, randomized, multicenter, comparative, dose-ranging,
placebo-controlled study to determine the safety and efficacy of MS-325
enhanced MRA for evaluation of aortoiliac occlusive disease in patients
with known or suspected peripheral vascular disease.
Epix Medical, Inc. and Mallinkrodt.

Co-investigator: National Multicenter Trial. Apr 1998 – 2007
Wallgraft endoprothesis iliac occlusive clinical trial.
Schneider (USA) Inc.

Principal Investigator: National Multicenter Trial. Nov 1997 – Dec 1997
A phase II study of the safety and preliminary efficacy of MS-325-
enhanced magnetic resonance angiography in carotid and peripheral arteries.
Epix Medical, Inc.

Collaborating Investigator: National Multicenter Trial. Feb 1997 – Feb 1998
A prospective, randomized comparison of percutaneous transluminal angioplasty (PTA) with or without the Corvita Endoluminal graft (CEG) used as immediate (primary) or late (suboptimal PTA) adjunctive therapy for the treatment of iliac artery occlusive disease.
Corvita Corporation.

Collaborating Investigator: National Multicenter Trial. 1993 – 1995
Thrombolysis or peripheral arterial surgery (TOPAS).
Abbott Laboratories.

Other Creative Products
Electronic/Media:

Morris CS. Kawasaki Disease. Vascular and Interventional Radiology.
American College of Radiology and Society of Interventional Radiology CD-ROM Series.
Sept, 2003.

Morris CS. Chronic Mesenteric Ischemia. Vascular and Interventional Radiology.
American College of Radiology and Society of Interventional Radiology CD-ROM Series.
Sept. 2003.

Participation in Corporate Agreements:

Philips HealthTech Agreements (as a radiologist in the department, I participate in research collaboration projects that allow us to maintain cutting edge technology for clinical service, teaching and research.)

1. Reference Site Agreement
I provide:
   a. Radiologist peer to peer education during customer site visits to UVMMC
   b. Product demonstrations during customer site visits to UVMMC
   c. Contribution to Image Library for visiting customers
   d. Follow-up discussions with peers

2. Master Research Agreement:
I provide:
   a. Pre-production testing for Beta upgrades
   b. Clinical observation and feedback on products
   c. Test sequences and image acquisition
   d. Software evaluation
   e. Protocol development for products

McKesson Luminary Agreement (results in institutional discounts on technology and service)

I provide:

a. User feedback for the development of Beta products
b. Radiology informatics workflow development
c. Participation in product evaluation surveys, product development discussions and focus groups
d. Site visit participation that includes product demonstrations and peer to peer discussions with McKesson customers.

ATTACHMENT C

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

DEPOSITION TRANSCRIPTS
Depositions and exhibits from Dr. Nicholson and Barbara Delio-Cox

EXPERT REPORTS
David Kessler Expert Report – Austin v. C. R. Bard, Inc. (9/27/2016)
David A Kessler Expert Report – MDL (3/03/2017)
David Garcia & Michael Streiff Expert Report - MDL (3/03/2017)
Suzanne Parisian Expert Report - MDL (3/03/2017)
Steven Hertz Expert Report - Barazza (2/10/2017)
Robert Vogelzang Expert Report - MDL (3/03/2017)
Robert Ritchie Expert Report - MDL (3/02/2017)
Robert McMeeking Expert Report - MDL (3/03/2017)
Rebecca Betetnsky Expert Report - MDL (3/03/2017)
Rebecca Betensky Expert Report- EX C- Bard DFMEA
Rebecca Betensky Expert Report - Barazza (2/10/2017)
Mark Eisenberg Expert Report - Barazza (2/10/2017)
David Bates Expert Report - Barazza (2/10/2017)
Expert Report -- Betensky -- 2017-02-10 (Barazza)
Expert Report -- Betensky -- 2017-03-03 (MDL) Exhibit C to Report.xlsx
Expert Report -- Betensky -- 2017-03-03 (MDL)
Expert Report -- Bates -- 2017-02-10 (Barraza)
Expert Report -- Eisenberg -- 2017-02-10 (Barazza)
Expert Report -- Garcia and Streiff -- 2017-03-03 (MDL)
Expert Report -- Hertz -- 2017-02-02 (Barazza)
Expert Report -- Kessler -- 2016-09-27 (MDL)
Expert Report -- Kessler -- 2017-03-03 (MDL)
Expert Report -- Kinney, Roberts, Kalva -- 03-06-2017 (MDL)
Expert Report -- McMeeking -- 2017-03-03 (MDL)
Expert Report -- Parisian -- 2017-03-03 (MDL)
Expert Report -- Ritchie -- 2017-03-02 (MDL)
Expert Report -- Vogelzang -- 2017-03-03 (MDL)
Bard MDL - Eisenberg Supplemental Report_Meridian Denali 4-7-17
Bard MDL - McMeeking - Supplemental Report_Meridian & Denali 4-7-17
Bard MDL - Parisian - Supplemental Report_Denali & Meridian 4-7-17
Bard MDL - Ritchie -Supplemental Report_Meridian & Denalit 4-7-17
Bard MDL - Vogelzang - Supplemental Report_Meridian & Denali 4-7-17
NOS - Expert_Testimony_(Meridian&Denali)

MEDICAL ARTICLES

Title	**Author(s)**
Scientific Session 1 IVC Filters, Venous Thromboembolic Disease	

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
Society of Interventional Radiology Responds to FDA Blood Clot Device (IVC Filter) Advisory	
ACR-SIR-SPR practice parameter for the performance of IVC filters (2014)	ACR SIR
ACR-SIR-SPR practice parameter for the performance of IVC filters (2016)	ACR SIR
ACR-SIR-SPR Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism (Updated 2016)	ACR-SIR-SPR
Retrievable Inferior Vena Cava Filters in Trauma Patients: Factors that Influence Removal Rate and An Argument for Institutional Protocols	Albrecht
Upcoming IVC Filter Data From the American Venous Registry [**not a peer-reviewed article**]	American Venous Forum
Prevalence and Clinical Consequences of Fracture and Fragment Migration of the Bard G2 Filter: Imaging and Clinical Follow-up in 684 Implantations	An
Comparison of Complication Rates Associated with Permanent and Retrievable Inferior Vena Cava Filters: A Review of the MAUDE Database	Andreoli
Systematic Review of the Use of Retrievable Inferior Vena Cava Filters	Angel
Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter	Asch
Inferior Vena Caval Filters: Review of a 26-year Single-Center Clinical Experience	Athanasoulis
Information Systems Can Prevent Errors and Improve Quality	Balas
Inferior Vena Cava Filters Indications, Safety, Effectiveness	Becker
Vena Cava Filter Migration: An unappreciated Complication. About Four Cases and Review of the Literature	Belenotti
Society of Interventional Radiology letter re: FDA Public Health Notification- Removing Retrievable Inferior Vena Cava Filters: Initial Communication	Benenati
Long-Term Retrievability of IVC Filters: Should We Abandon Permanent Devices?	Berczi
Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days	Binkert
Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study	Binkert
In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters	Bjarnason
Indwelling and Retrieval Complications of Denali and Celect Infrarenal Vena Cava Filters	Bos
Medical Device Epidemiology and Surveillance – Patient Safety is the Bottom Line	Brown

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters	Cantwell
Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Caplin
Complications Encountered with the Use of the Greenfield Filter	Carabasi
Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma	Carlin
Update on Vena Cava Filters	Carman
G2 Inferior Vena Cava Filter Retrievability and Safety	Charles
Technical and Financial Feasibility of an Inferior Vena Cava Filter Retrieval Program at a level One Trauma Center	Charlton-Ouw
Prophylactic Inferior Vena Cava Filters: Do They Make a Difference in Trauma Patients? (abstract only)	Cherry
Complications of vena cava filters: A comprehensive clinical review	Cipolla
CIRA Statement on IVC Filter Safety Concerns noted by Health Canada	CIRA
Open Surgical Inferior Vena Cava Filter Retrieval for Caval Perforation and a Novel Technique for Minimal Cavotomy Filter Extraction	Connelly
Vena Cava Filters and Inferior Vena Cava Thrombosis	Corriere
IVC Filters, Venous Thromboembolic Disease	Cura
Use of a Retrievable Vena Cava Filter with Low-Intensity Anticoagulation for Prevention of Pulmonary Embolism in Patients with Cancer: An Observational Study in 106 Cases	Damascelli
Primary Care Atrial Fibrillation Service – Outcomes from Consultant-Led Anticoagulation Assessment Clinics in the Primary Care Setting	Das
TrapEase Inferior Vena Cava Filter Placed via the Basilic Arm Vein: A New Antecubital Access	Davison
Prophylactic Inferior Vena Cava Filters Prevent Pulmonary Embolisms in High-Risk Patients Undergoing Major Spinal Surgery	Dazley
Initial Australian Experience with the Recovery Inferior Vena Cava Filter in Patients with Increased Risk of Thromboembolic Disease	De Villiers
A Clinical Trial of Vena Caval Filters in the Prevention of Pulmonary Embolism in Patients with Proximal Deep-Vein Thrombosis	Decousus
Complications of Indwelling Retrievable Versus Permanent Inferior Vena Cava Filters	Desai

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
Fragmentation, Embolization, and Left Vefitricular Perforation of a Recovery Filter	Desjardin
Case Report – Fragmentation, Embolization, and Left Ventricular Perforation of a Recovery Filter	Desjardin
Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type	Deso
Removal of Fractured Inferior Vena Cava Filters: Feasibility and Outcomes	Dinglasan
Complicated Inferior Vena Cava Filter Retrievals – Associated Factors Identified on Preretrieval CT	Dinglasan
Outcomes of Patients Requiring Insertion of an Inferior Vena Cava Filter – A Retrospective Observational Study	Duffett
Perforation of the IVC - Rule Rather Than Exception After Longer Indwelling Times for the Gunther Tulip and Celect Retrievable Filters	Durack
Placement and Removal of Inferior Vena Cava Filters – National Trends in the Medicare Population	Duszak
Clinical Experience with the Antecubital Simon Nitinol IVC Filter	Engmann
Comparison of Dabigatran and Warfarin in Patients with Atrial Fibrillation and Valvular Heart Disease	Ezekowitz
Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use	FDA
FDA Safety Communication: Removing Retrievable Inferior Vena Cava Filters	FDA
Percutaneous Inferior Vena Caval Filters: Follow up of Seven Designs in 320 Patients	Ferris
Migration of the Gunther Tulip inferior vena cava filter to the chest	Galhotra
Retrievable Inferior Vena Cava Filters Are Rarely Removed	Gaspard
Improving Retrieval Rates of Temporary Inferior Vena Cava Filters	Gasparis
Medical Literature and Vena Cava Filters	Girard
Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter	Grande
Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Grassi
Inferior Vena Caval Filters Analysis of Five Currently Available Devices	Grassi
Vena Caval Occlusion after Simon Nitinol Filter Placement-Identification with MR Imaging in Pati	Grassi
Evolution of Hook Design for Fixation of the Titanium Greenfield Filter	Greenfield

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
Extended Evaluation of the Titanium Greenfield Vena Caval Filter - Copy	Greenfield
The Percutaneous Greenfield Filter- Outcomes and Practice Patterns	Greenfield
Immunization Information Systems to Increase Vaccination Rates – A Community Guide Systematic Review	Groom
Patients' Perspectives on the Role of Their General Practitioner After Receiving an Advanced Cancer Diagnosis	Halkett
Long-Term Follow-up of the Antheor Inferior Vena Cava Filter	Harries
Safety Alert – Inferior Vena Cava Filters – Risk of Serious Complications	Health Canada
Safety and Efficacy of the Gunther Tulip Retrievable Vena Cava Filter: Midterm Outcomes	Hoffer
Retrieval of the Recovery Filters after Arm Perforation, Fracture, and Migration to the Right	Hull
Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration	Hull
Advanced Techniques for Removal of Retrievable Inferior Vena Cava Filters	Iliescu
A Systematic Method for Follow-up Improves Removal Rates for Retrievable Inferior Vena Cava Filters in a Trauma Patient Population	Irwin
A Measured Approach to Vena Cava Filter Use -- Respect Rather than Regret	Jaff
Single Institution Prospective Evaluation of the Over-the-Wire Greenfield Vena Caval Filter	Johnson
Vena Cava Filter Fracture: Unplanned Obsolescence	Johnson
Abstract Asymptomatic Patients With Inferior Vena Cava Filter Penetration Through the Wall May be Managed Conservatively	Journal of Vascular Surgery
Suprarenal Inferior Vena Cava Filters- A 20-Year Single-Center Experience	Kalva
Recovery Vena Cava Filter: Experience in 96 Patients	Kalva
Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: an AAST Multicenter Study	Karmy-Jones
A Dedicated Inferior Vena Cava Filter Service Line: How to Optimize Your Practice	Karp
Inferior Vena Cava Filters – In Vitro Comparison of Clot Trapping and Flow Dynamics	Katsamouris
SIR Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference	Kaufman
Development of a Research Agenda for Inferior Vena Cava Filters: Proceedings from a Multidisciplinary Research Consensus Panel	Kaufman

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
The Value of Rotational Venography Versus Anterior-Posterior Venography in 100 Consecutive IVC Filter Retrievals	Kiefer
IVC Filters: Challenges and Future Directions	Kiguchi
A Comparison of Clinical Outcomes with Retrievable and Permanent Inferior Vena Cava Filters	Kim
Update on Inferior Vena Cava Filters	Kinney
Institutional Protocol Improves Retrievable Inferior Vena Cava Filter Recovery Rate	Ko
Bard Denali IVC Filter Fracture and Embolization	Kuo
Case Report – Emergency Retrieval of a G2 Filter after Complete Migration into the Right Ventricle	Kuo
Complex Retrieval of Fractured, Embedded, and Penetrating Inferior Vena Cava Filters: A Prospective Study with Histologic and Electron Microscopic Analysis	Kuo
High-risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications	Kuo
National Trends in Utilization of Inferior Vena Cava Filters in the United States, 2000 – 2009	Kuy
Managing with Pacemakers and Implantable Cardioverter Defibrillators	Lampert
Results of Long-Term Venacavography Study After Placement of a Greenfield Vena Caval	Lang
Migration of the Simon Nitinol Vena Cava Filter to the Chest	LaPlante
In Vitro Hemodynamic Evaluation of a Simon Nitinol Vena Cava Filter	Leask
The CIRSE Retrievable IVC Filter Registry: Retrieval Success Rates in Practice	Lee
Screening for Abdominal Aortic Aneurysm – US Preventative Services Task Force Recommendation Statement	LeFevre
Abstract – A Prospective Study of 467 IVC Filter Placements – Is There a Difference Between Optional and Permanent Filters	Lewandowski
Removal of the G2 Filter Differences between Implantation Times Greater and Less than 180 Days	Lynch
Balloon-assisted Removal of Tilted Inferior Vena Cava Filters with Embedded Tips	Lynch
A Method for Following Patients with Retrievable Inferior Vena Cava Filters: Results and Lessons Learned from the First 1100 Patients	Lynch
Bard Denali Filter Fractures	Majdalany
Persistent Abdominal Pain Caused by an Inferior Vena Cava Filter Protruding Into the D	Malgar
Collaborative Modeling of the Benefits and Harms Associated with Different US Breast Cancer Screening Strategies	Mandelblatt

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
Complications of the Nitinol Vena Caval Filter	McCowan
Complications of Celect, Gunther Tulip, and Greenfield Inferior Vena Cava Filters on CT Follow-up A Single-Institution Experience	McLoney
Case Report – Expectoration of An Inferior Vena Cava Filter Strut	Mehanni
Indications for Vena Cava Filters for Recurrent DVT	Miller
CT Evaluation of Kimray-Greenfield Filter Complications	Miller
Temporary and Retrievable Inferior Vena Cava Filters: Current Status	Millward
Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters	Millward
Improving Inferior Vena Cava Filter Retrieval Rates: Impact of a Dedicated Inferior Vena Cava Filter Clinic	Minocha
Fracture Rate and Serious Complications of Vena Cava Filters	Mitsunaga
Abstract – Complication and Retrieval Rates of Inferior Vena Cava Filters, A Single-Center Retrospective Study	Mohla
Decision Analysis of Retrievable Inferior Vena Cava Filters in Patients Without Pulmonary Embolism	Morales
Realistic expectations and candidate selection for entry level vascular technologist in a busy laboratory	Mutyala
Letter to the Editor - A Complication of a G2 Bard Filter	Nazzal
Complications Related to Inferior Vena Cava Filters: A Single-Center Experience	Nazzal
Screen for Breast Cancer – An Update for the US Preventative Services Task Force	Nelson
Long-term Follow-up of the Birds Nest IVC Filter	Nicholson
Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac	Nicholson
Correction to Article About Prevalence of Fracture and Fragment Embolization	Nicholson
Refrain, Recover, Replace	Nicholson
Removal of Retrievable Inferior Vana Cave Filters with Compound Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall	Oh
Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval	Oliva
The Gunther-Tulip Retrievable IVC Filter: Clinical Experience in 118 Consecutive Patients	Ota
Intracardiac Migration of Inferior Vena Cava Filters	Owens
Endovascular Retrieval of Intracardiac Inferior Vena Cava Filters: A Review of Published Techniques	Owens

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
Comparative In Vitro Evaluation of the Nitinol Inferior Vena Cava Filter	Palestrant
Abstract – Complication and Retrieval Rates of Inferior Vena Cava Filters, A Single Center Retrospective Study	Parker
Predictors of Attempted Inferior Vena Cava Filter Retrievals in a Tertiary Care Centre	Peterson
Case Report – Cardiac Perforation by Migrated Fractured Strut of Inferior Vena Cava Filter Mimicking Acute Coronary Syndrome	Piercecchi
Cost-Effectiveness Analyses of Colorectal Cancer Screening – A Systematic Review for the US Preventative Services Task Force	Pignone
Long-term results of the Simon Nitinol inferior vena cava filter	Poletti
Eight-year follow up of patients with permanent vena cava filters in the prevention of PE	PREPIC Group
In Vivo Evaluation of Vena Caval Filters- Can Function Be Linked to Design Characteristics	Proctor
Complications Associated with WC Filters - A Large, Single Institution Review	Purcell
Aortic Pseudoaneurysm after Penetration by a Simon Nitinol Inferior Vena Cava Filter	Putterman
Complications of Inferior Vena Cava Filters	Ray
Outcomes with Retrievable Inferior Vena Cava Filters: A Multicenter Study	Ray
Medical Devices and the FDA Approval Process	Redberg
A Single Center Experience with Retrievable IVC Filters	Renno
Improved Recovery of Prophylactic Inferior Vena Cava Filters in Trauma Patients: The Results of a Dedicated Filter Registry and Critical Pathway for Filter Removal	Rogers
Gunther Tulip and Celect IVC Filters in Multiple Trauma Patients	Rosenthal
Case Report – Right Ventricular Migration of a Recovery IVC Filter's Fractured Wire with Subsequent Pericardial Tamponade	Saeed
Frequent Fracture of TrapEase Inferior Vena Cava Filters: A Long-term Follow-up Assessment	Sano
Association Between Inferior Vena Cava Filter Insertion in Trauma Patients and In-Hospital and Overall Mortality	Sarosiek
Indications, Complications, and Management of Inferior Vena Cava Filters	Sarosiek
Case Report – Inferior Vena Cava Filter Removal After Prolonged Dwell Time of 2310 Days	Shah
Case Report – Delayed Complications of Inferior Vena Cava Filters – Case Report and Literature Review	Shang
Optional Vena Cava Filter Use in the Elderly Population	Shaw

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	**Author(s)**
Simon Nitinol Inferior Vena Cava Filter Initial Clinical Experience	Simon
Modeling Blood Flow in a Tilted Inferior Vena Cava Filter – Does Tilt Adversely Affect Hemodynamics	Singer
Vena Caval Filters	Smith
Is Market Growth of Vena Cava Filters Justified	Smouse
How Have Your Protocols for IVC Filter Placement, Monitoring, and Retrieval Changed in the Past Several Years? [**not a peer-reviewed article**]	Smouse
Retrieval of Tip-Embedded IVC Filters by Using the Endobronchial Forceps	Stavropoulos
The DENALI Trial An Interim Analysis of a Prospective Multicenter Study	Stavropoulos
Outcome and Complications of Retrievable Inferior Vena Cava Filters	Stein
Impact of vena cava filters on in-hospital case fatality rate from PE	Stein
Vena cava filters in unstable elderly patients with acute PE	Stein
Complications of Vascular Access Procedures in Patients with Vena Cava Filters	Streib
Ask the Experts: What is Your Practice's Current IVC Filter Retrieval Protocol, and in Which Cases Do You Deviate From It? [**not a peer-reviewed article**]	Sudheendra
Improving Inferior Vena Cava Filter Retrieval Rates with the Define, Measure, Analyze, Improve, Control Methodology	Sutphin
Experience with Vena Cava Filters at a Large Community Hospital and Level I Trauma Center – Indications, Complications, and Compliance Barriers	Swami
Medical Monitoring of Asbestos-Exposed Workers – Experience from Poland	Swiatkowska
Personalized Estimates of Benefit from Preventative Care Guidelines – A Proof of Concept	Taksler
Fracture and Distant Migration of the Bard Recovery Filter - A Retrospective Review of 363 Implantations for Potentially Life-Threatening Complications	Tam
Out of Sight, Out of Mind: An Audit of Inferior Vena Cava Filter Insertion and Clinical Follow up in An Australian Institution and Literature Review	Tan
Temporary inferior vena cava filter indications, retrieval rates, and follow-up management at a multicenter tertiary care	Tao
Vena Tech Vena Cava Filter: Experience and Early Follow-Up	Taylor
Ten-Year Experience of Retrievable Inferior Vena Cava Filters in a Tertiary Referral Center	Tse

Christopher S. Morris, M.D.
LIST OF MATERIALS RECEIVED

Title	Author(s)
British Society of Interventional Radiology (BSIR) Inferior Vena Cava (IVC) Filter Registry	Uberoi
The Guide to Clinical Preventative Services	US Preventative Services Task Force
Case Report – Spontaneous Migration of an Inferior Vena Cava Filter Resulting in Cardiac Tamponade and Percutaneous Filter Retrieval	Vergara
Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts	Vijay
Case Report – Recurrent Fracture of a Recovery Inferior Vena Cava Filter with Pulmonary Migration	Vossen
Commentary – Inferior Vena Cava Filters in Trauma Patients – For Whom the Benefit Tolls	Waltz
Outcomes after vena cava filter use in noncancer patients with acute venous thromboembolism	White
A Multidisciplinary Quality Improvement Program Increases the Inferior Vena Cava Filter Retrieval Rate	Winters
Medical Monitoring – A Beneficial Remedy for Residents Living Near an Environmental Hazard Site	Wones
Reporting the Impact of Inferior Vena Cava Perforation By Filters	Wood
Vena caval filters for the prevention of pulmonary embolism	Young
Effectiveness of Inferior Vena Cava Filters without Anticoagulation Therapy for Prophylaxis of Recurrent Pulmonary Embolism	Zekster
Retrospective Review of 120 Celect Inferior Vena Cava Filter Retrievals Experience at a Single Institution	Zhou
Penetration of Celect Inferior Vena Cava Filters Retrospective Review of CT Scans in 265 Patients	Zhou
Retrievability and Device-Related Complications of the G2 Filter: A Retrospective Study of 139 Filter Retrievals	Zhu